

MEETING  
STATE OF CALIFORNIA  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
CALIFORNIA ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM  
SCIENTIFIC GUIDANCE PANEL

ELIHU M. HARRIS STATE BUILDING  
1515 CLAY STREET  
ROOM 1305  
OAKLAND, CALIFORNIA

FRIDAY, OCTOBER 24, 2008  
10:07 A.M.

JAMES F. PETERS, CSR, RPR  
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APPEARANCES

PANEL MEMBERS

Dr. Edward Moreno, Chairperson

Dr. Asa Bradman

Dr. B. Dwight Culver (via teleconference)

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer (via teleconference)

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

Mr. David Berger, Health Education Consultant, Safer  
Alternative Assessment and Biomonitoring Section (via  
teleconference)

Ms. Sara Hoover, Chief, Safer Alternative Assessment and  
Biomonitoring Section

Dr. Rachel Roisman, Public Health Medical Officer, Safer  
Alternative Assessment and Biomonitoring Section

Dr. Martha Sandy, Chief, Cancer Toxicology and  
Epidemiology Section

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard  
Assessment Branch

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APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Peter Flessel, Chief, Environmental Health Laboratory  
Branch

Ms. Diana Lee, Research Scientist

Dr. Michael Lipsett, Chief, Exposure Assessment Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonwealth

Dr. Randy Curtin, Centers for Disease Control and  
Prevention

Ms. Gretchen Lee, Breast Cancer Fund

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1 PROCEEDINGS

2 OEHHA DIRECTOR DENTON: Good morning to everyone  
3 here in Oakland and down in Los Angeles. My name is Joan  
4 Denton and I'm the Director of OEHHA. And we appreciate  
5 you being here. And for those individuals in Los Angeles,  
6 we appreciate you attending this meeting from that  
7 location.

8 This is unusual, and we're expecting this to be a  
9 one-time event, where we will have a meeting convened from  
10 two locations. The explanation for the meeting happening  
11 this way this time is that it wasn't until, what was it,  
12 three weeks ago that the budget was signed. So the  
13 meeting was off and on. And we couldn't really plan on it  
14 until the budget was signed.

15 Consequently, we didn't want to impose on the  
16 individuals from the south coast to be able to do  
17 traveling when we had an agenda for four hours. So we put  
18 together this meeting, in which we're here in Oakland and  
19 there are two of the Panel members down in Los Angeles.

20 And in just a minute, I will have the Panel  
21 members introduce themselves. In fact, that's probably a  
22 good idea right now.

23 So we'll start here in Sacramento. And, Marion,  
24 maybe we could start with you. Introduce yourself.

25 PANEL MEMBER KAVANAUGH-LYNCH: Sure. I'm Marion

1 Kavanaugh-Lynch. I'm the Director of the California  
2 Breast Cancer Research Program housed at University of  
3 California, Office of the President.

4 PANEL MEMBER WILSON: Michael Wilson, a research  
5 scientist at the Center for Occupational and Environmental  
6 Health housed at UC Berkeley.

7 PANEL MEMBER BRADMAN: Asa Bradman at the Center  
8 for Childrens' Environmental Health Research at UC  
9 Berkeley.

10 PANEL MEMBER QUINT: Julia Quint, retired from  
11 the California Department of Public Health.

12 PANEL MEMBER MCKONE: Tom McKone with the  
13 University of California at Berkeley, School of Public  
14 Health, and also with the Lawrence-Berkeley National  
15 Laboratory.

16 PANEL MEMBER SOLOMON: Gina Solomon, a senior  
17 scientist with the Natural Resources Defense Council, and  
18 also on the faculty at UCSF in the Division of  
19 Occupational and Environmental Medicine.

20 OEHHA DIRECTOR DENTON: And you'll notice that  
21 Dr. Moreno did not introduce himself and is not here.  
22 He's expected to arrive probably around 11 o'clock. So  
23 after I make my introductory remarks, then I'll turn it  
24 over to Asa, who will conduct the meeting for Dr. Moreno  
25 until he arrives.

1           Okay. Dr. Luderer is going to be facilitating  
2 the meeting down in Los Angeles.

3           And could you introduce yourselves down there.

4           PANEL MEMBER LUDERER: Yeah. I am Ulricke  
5 Luderer. I'm at the University of California, Irvine,  
6 Center for Occupational and Environmental Health. And  
7 that's actually where we are sitting as we speak, not in  
8 Los Angeles. We're in Orange County.

9           PANEL MEMBER CULVER: My name's Dwight Culver,  
10 University of California, Irvine, Department of  
11 Epidemiology.

12           OEHHA DIRECTOR DENTON: Okay. So just a couple  
13 of things I want to mention before I turn it over to Asa.

14           First of all, I'm required to tell you if there's  
15 an emergency what you should do. And, that is, you should  
16 go out either door and look either right or left and there  
17 will be exit signs, and you follow people going to the  
18 exits. So that's your emergency information.

19           The restrooms are actually down here to the  
20 right, but you need a card. So you need to pick up a card  
21 from the back table. You go to the end of the hall and  
22 make a left and you'll see them right there on the left.

23           Okay. I just want to mention or just to remind  
24 you what happened at our last Science Guidance meeting and  
25 then tell you what our plan is for this Science Guidance

1 meeting. Again, it's scheduled to go until 2:30, with a  
2 break for lunch.

3 But at the last Science Guidance Panel, we had it  
4 here in Oakland in June, June 10th. And the focus of the  
5 meeting -- actually had a workshop the previous day  
6 followed by a Science Guidance Panel meeting the next day.  
7 And the focus of the meeting was on chemical selection and  
8 also laboratory capacity.

9 The purpose of this meeting is to get a program  
10 update, which will be the first item on the agenda,  
11 followed by a discussion and a presentation about sampling  
12 design. And then in the afternoon, we'll be hearing some  
13 updates about laboratory work. So that's what's going to  
14 happen this meeting.

15 The December meeting will be devoted to chemical  
16 selection. And will be a major, if not only, agenda  
17 topic.

18 So I think, at this point, I -- hopefully,  
19 everyone has picked up a copy of the agenda. And I think  
20 Dr. Asa Bradman here is going to go a little bit over the  
21 agenda, so I won't duplicate what he's going to say.

22 And I will turn it over to you.

23 PANEL MEMBER BRADMAN: First, I want to welcome  
24 everybody here on behalf of the Panel, welcome the staff  
25 and public participants.



1           Just to review a few of the plans for today and  
2 also some things to take note of in terms of this kind of  
3 unique meeting situation where we have people both in  
4 northern and southern California. One key goal is to make  
5 sure that the discussion here is audible to all  
6 participants. So if anyone has any trouble hearing at any  
7 point, particularly those in southern California, please  
8 speak up and let us know. In some cases, it will be  
9 necessary to pass these little mikes around so people can  
10 hear what you're saying. And, again, that's important.

11           Also, as part of that effort, please be sure to  
12 identify yourself before you speak. That's important for  
13 the person taking notes and also so we know who's talking.

14           There's a few points where we'll ask about  
15 whether there's any questions. And there'll also be  
16 several opportunities for public input during the meeting.  
17 Those will occur perhaps at the presentation on sample  
18 design in the morning and also after the laboratory update  
19 in the afternoon.

20           For those of you from the public who want to make  
21 comments in northern California, you can place questions  
22 on the card in the back room; and in southern California  
23 you can leave a card with David Berger. So if there's any  
24 questions about that, please let us know.

25           Dr. Denton mentioned the agenda, which most of

1 you have a copy of. We'll focus on the update on program  
2 activities, presentation of the sample design options, and  
3 an update on laboratory activities.

4 Everyone should have materials for the day. If  
5 you're a Panel member, you should have a packet. And for  
6 others, information is available on the website or in the  
7 back of the room.

8 We ask that you keep comments today focused  
9 specifically on the agenda today. We don't have that much  
10 time and there's a lot to cover.

11 There will be a lunch break, and there will also  
12 be a break at midday for lunch. And just a reminder,  
13 everyone's on their own for lunch.

14 So I think I've covered all the key points for  
15 today.

16 OEHHA DIRECTOR DENTON: Just one other thing to  
17 add, that the meeting notes, the meeting transcript will  
18 be transcribed and put on our website for the members of  
19 the public who are not able to attend this meeting.

20 And here in Oakland we have about 30 people in  
21 the room, including the Panel.

22 And, Dr. Luderer, do you also have members of the  
23 public in your location?

24 PANEL MEMBER LUDERER: No, we do not. There are  
25 only three of us here, David Berger and Dr. Culver and

1 myself.

2 OEHHA DIRECTOR DENTON: Okay. All right.

3 PANEL MEMBER BRADMAN: Well, with that, I would  
4 like to introduce Dr. Lipsett, who is Chief of the  
5 Exposure Assessment Section of the Environmental Health  
6 Investigations Branch at the California Department of  
7 Public Health. And he's been the lead on the California  
8 Biomonitoring Program and he'll update the Panel on  
9 program activities since our last meeting.

10 So, again, please let us know if you have any  
11 trouble hearing.

12 (Thereupon an overhead presentation was  
13 Presented as follows.)

14 DR. LIPSETT: Dr. Denton and Members of the  
15 Panel, good morning.

16 I wanted to start with a brief announcement; and,  
17 that is, that there have been a few minor changes that  
18 have been made on the presentations. So that what you're  
19 going to be seeing on the screen is a little bit different  
20 from what's in the handouts. But the corrected  
21 versions -- all the corrected versions will be posted on  
22 the web and available early next week.

23 --o0o--

24 DR. LIPSETT: Okay. Could I ask a procedural  
25 question. Would the members who are down south -- will

1 they see as I switch the slides, or do I have to announce  
2 as I'm switching slides?

3 MS. HOOVER: No, you need to announce. Say "next  
4 slide."

5 DR. LIPSETT: Okay. I'm on the next slide that  
6 says budget status.

7 Okay. The current budget status for the program  
8 is that our Department has hired eight people for the  
9 program, OEHHA has hired two, and DTSC has hired two. The  
10 ongoing base budgets are listed there on the right-hand  
11 side of the slide: About 1.025 million for us; about .663  
12 million for OEHHA; and DTSC, about 368,000.

13 Now, I guess the good news for the budget process  
14 is that we did not sustain any significant cuts to the  
15 budget. The bad news is that we're no longer on the  
16 General Fund -- although some people might view that as  
17 good news -- and we've been switched to the fund that is  
18 administered by the Department of Toxic Substances Control  
19 and it's called the Toxic Substances Control Account.

20 And as part of the budgetary process, the  
21 Governor issued an Executive Order that required all  
22 General Fund contracts to be suspended, which is what we  
23 did with the contracts that we had, for example, with the  
24 Centers for Disease Control. But this order was lifted  
25 this week, and so we hope to be able to continue to work

1 on these different projects with the CDC and with UC.

2 Next slide.

3 --o0o--

4 PANEL MEMBER WILSON: Mike?

5 DR. LIPSETT: Yes.

6 PANEL MEMBER WILSON: Sorry for the Interruption.

7 Can people hear in the back Michael's

8 presentation?

9 MS. HOOVER: Project, Michael.

10 (Laughter.)

11 DR. LIPSETT: All right.

12 Okay. I'm on the next slide that says Program  
13 Activities. Our department has been working continuously  
14 with the CDC on issues related to the statewide sample  
15 design. It's an ongoing iterative process that we are  
16 relying very heavily on the expertise of the CDC in their  
17 NHANES program. And we're going to hear a little bit  
18 later today from Dr. Randy Curtin, a senior statistician  
19 with NCHS, who's played a pivotal role in helping us with  
20 a number of the design issues.

21 One of the things that we would like to ask the  
22 Panel, however, in this regard -- I'll just put this out  
23 now, maybe you can discuss it later -- is that we would  
24 like to have a small work group of Panel members similar  
25 to the Chemical Selection Work Group to be interacting

1 with us periodically as we're going through the design,  
2 either for a statewide sample or, what is more likely in  
3 the shorter term, for community types of smaller scale  
4 studies.

5           So I just want to put that request out there for  
6 now, and maybe we can discuss it a little bit later.

7           Now, in terms of the questionnaire development,  
8 we have been working on specific modules for  
9 questionnaires that will be used for either a statewide  
10 sample or community types of studies. We're focusing on  
11 demographic medical history and specific chemical groups  
12 that we think are going to be included within the  
13 Biomonitoring Program. And so we've started focusing  
14 specifically on flame retardants and questionnaires that  
15 might be related to exposures to flame retardants.

16           Then we've also been working on developing field  
17 protocols and specifically a cost model with the CDC about  
18 what kinds of expenditures and resources would be needed  
19 in order to be able to, you know, collect field samples,  
20 administer questionnaires through the recruitment. And  
21 this cost model is something that could be applied to  
22 estimate the costs that we'd need both for doing community  
23 types of studies as well as the statewide survey. And,  
24 again, this is an iterative type of process where the  
25 design of the survey dictates to some extent the costs

1 that are going to be incurred. And our budget, in turn,  
2 will restrict what we can -- what it is that we're able to  
3 actually undertake in the field. And Dr. Curtin is going  
4 to talk about these sorts of trade-offs in his  
5 presentation.

6 And in terms of laboratory activities, this is  
7 the subject of this afternoon's discussion. So I'm going  
8 to postpone that for now.

9 --o0o--

10 DR. LIPSETT: And then, finally, in terms of  
11 chemical selection, at the June 2008 meeting, the Panel  
12 named eight chemical groups -- I'm on the next slide, for  
13 you in southern California -- the Panel named eight  
14 chemical groups to investigate as potential designated  
15 chemicals; and also identified some chemicals for further  
16 investigation, including common household products and  
17 NDMA. And with the Chemical Selection Work Group, our  
18 staff have been meeting pretty regularly, and we hope to  
19 discuss these issues at great length at the December 2008  
20 Panel meeting.

21 So I think with that -- I don't know if the Panel  
22 members have any questions about the program at this  
23 point.

24 PANEL MEMBER McKONE: A brief question. Since  
25 there was a stop-work order in place from roughly end of

1 July, has that -- so that you couldn't work with the CDC  
2 particularly. How much has that set things behind, or has  
3 that really been able to be worked around?

4 DR. LIPSETT: Well, probably you could say maybe  
5 about a month and a half, something like that. But we did  
6 have some work with the CDC that was ongoing where some of  
7 the members of the work group there, who are not  
8 specifically funded through this contract but who are  
9 full-time salaried staff, were willing to work on this  
10 anyhow. So we didn't have the full complement of people,  
11 but we had a subset of those working on this during that  
12 period.

13 PANEL MEMBER BRADMAN: Just a reminder, Tom.  
14 Please identify yourself for the record.

15 PANEL MEMBER McKONE: Right.

16 PANEL MEMBER QUINT: I'm Julia Quint.

17 I am curious about the new funding source. Is  
18 that a revenue-generating source from DTSC or what -- the  
19 toxics, the new switch from General Fund to --

20 DR. LIPSETT: It's a fee-based source.

21 PANEL MEMBER QUINT: Fee-based.

22 DR. LIPSETT: Right.

23 PANEL MEMBER QUINT: Okay.

24 DR. LIPSETT: It is fee-based. And the way it  
25 was set up is that both OEHHA and CDPH in principle would



1 be able to directly access that fund to support our  
2 activities.

3 PANEL MEMBER QUINT: Okay.

4 OEHHA DIRECTOR DENTON: This is Joan Denton.

5 It's a fee which is placed on generators of  
6 hazardous waste.

7 PANEL MEMBER QUINT: Oh, okay.

8 PANEL MEMBER WILSON: This is Mike Wilson.

9 As a related question, do you have as a --

10 MS. HOOVER: Hang on, Mike.

11 PANEL MEMBER WILSON: Oh, okay.

12 Okay. Mike Wilson. And is that -- do you see  
13 that as a more or less stable funding source, as --

14 (Laughter.)

15 PANEL MEMBER WILSON: -- vis-a-vis the General  
16 Fund, I guess, question?

17 OEHHA DIRECTOR DENTON: I think one thing to be  
18 said is that TSCA is a DTSC fund. And DTSC -- was there  
19 people here from DTSC? But it's a fund which is, you  
20 know, maintained by DTSC and they control the fund. I  
21 think the thought has been that that -- I mean, I don't  
22 know any excellent funding source at this point. And it  
23 has not been thought that that fund is all that stable.  
24 So I don't know if you want to -- but DTSC is really  
25 the -- that is the agency that has that fund and could

1 speak more to it.

2 DR. LIPSETT: Yeah. And my understanding from  
3 talking to some of the DTSC managers is that they view  
4 this fund as declining in revenues as well over the course  
5 of the next few years. So from the standpoint of, well,  
6 is this a growth fund? No.

7 (Laughter.)

8 PANEL MEMBER QUINT: That's a good thing. It  
9 means less hazardous waste, so that's good.

10 MS. HOOVER: Check with southern California.

11 PANEL MEMBER BRADMAN: Are there any questions or  
12 comments from the people in southern California?

13 PANEL MEMBER LUDERER: Yeah, hi. This is Ulricke  
14 Luderer.

15 I have just a question about the questionnaire  
16 development. And Michael mentioned that questions are  
17 being developed about demographics and medical history and  
18 some --

19 PANEL MEMBER BRADMAN: Hello.

20 MS. HOOVER: Hit "mute" on ours while she's  
21 speaking.

22 PANEL MEMBER LUDERER: Can you hear me?

23 PANEL MEMBER BRADMAN: We can now.

24 PANEL MEMBER LUDERER: Hello.

25 PANEL MEMBER BRADMAN: If you could repeat your

1 question.

2 MS. HOOVER: Yeah, you've got to unmute --

3 PANEL MEMBER BRADMAN: Can you repeat your  
4 question.

5 PANEL MEMBER LUDERER: Yes, I will.

6 I just had a question about questionnaire  
7 development. And Michael mentioned some categories that  
8 were currently being worked on in terms of the  
9 questionnaire. And I was wondering, is there going -- are  
10 you planning on having a meeting of the Scientific  
11 Guidance Panel that will be devoted more to really  
12 focusing on the questionnaire and the types of questions  
13 that will be asked or is that something that will be  
14 discussed potentially more today or at the December  
15 meeting?

16 DR. LIPSETT: Asa, I'm unmuting it -- it's  
17 unmuted now.

18 (Laughter.)

19 DR. LIPSETT: Yeah, we're having a dueling muting  
20 thing up here.

21 (Laughter.)

22 DR. LIPSETT: I think what we would like to do is  
23 with a work group from the Panel -- well, this is one  
24 aspect of the study design that we would like to work with  
25 a smaller subgroup on initially and then bring this to the

1 Panel perhaps for some of the meeting in December. But  
2 certainly this is the kind of thing that we would want  
3 your input on.

4 PANEL MEMBER LUDERER: Thank you.

5 PANEL MEMBER McKONE: Are we on? Never know.

6 DR. LIPSETT: You're on.

7 PANEL MEMBER McKONE: Remember, you had talked  
8 about setting --

9 OEHHA DIRECTOR DENTON: Tom, you want to  
10 introduce yourself.

11 PANEL MEMBER McKONE: Oh, I'm Tom McKone.

12 You had talked about setting up another  
13 sub-panel. About what timeframe are you thinking of doing  
14 that? Before the next full meeting, or would that be an  
15 activity in December that we would plan for, you know, to  
16 set up a -- or to discuss the formation of a subcommittee?  
17 Or is that something we should do today, actually talk  
18 about a subcommittee for the strategy of data collection  
19 and sampling?

20 DR. LIPSETT: Well, we were hoping that you would  
21 take some time today to discuss it. And hopefully we'll  
22 have at least a couple of volunteers.

23 PANEL MEMBER BRADMAN: So any comments -- any  
24 more comments related to this presentation?

25 Any discussion on Michael's points or requests at

1 this point?

2 I guess we'll defer discussion about the small  
3 work groups until later today.

4 DR. LIPSETT: All right.

5 PANEL MEMBER BRADMAN: So I think, at this point  
6 then, we're ready for Dr. Curtin's presentation.

7 Dr. Curtin, are you there?

8 DR. CURTIN: Yes, I am.

9 PANEL MEMBER BRADMAN: Okay. Are there -- I  
10 assume there's a presentation linked to that?

11 MS. HOOVER: Yeah, in southern California they  
12 should load.

13 PANEL MEMBER BRADMAN: In southern California you  
14 should be loading up the PowerPoint presentation for Dr.  
15 Curtin's talk.

16 And all of us should mute our phones during the  
17 presentation.

18 MS. HOOVER: But not yet.

19 PANEL MEMBER BRADMAN: But not yet.

20 DR. LIPSETT: Not yet. I wanted to just  
21 introduce him briefly.

22 PANEL MEMBER BRADMAN: Okay. Go ahead.

23 OEHHA DIRECTOR DENTON: Good idea.

24 DR. LIPSETT: Okay. So does the southern  
25 California group have Randy's slide show up yet?



1 overview.

2 I'll be breaking the presentation up today into  
3 three different sections:

4 Some of the basics of sample design.

5 Then a little bit about implications for a  
6 statewide study for California.

7 And then the third will be designing a community  
8 study, which is also sort of part of the net to structure  
9 the statewide study as well.

10 In between each of these, I'll give a moment for  
11 questions and then there'll be questions at the end.

12 I'll probably apologize in advance a little bit.  
13 I'm never sure with the type of audience whether I'm doing  
14 things too simplistic or too complicated. But hopefully  
15 on the average it will be okay.

16 --o0o--

17 DR. CURTIN: On the next slide -- okay, let me  
18 just -- I messed up my thing, so let me go back into it  
19 and make sure.

20 The next slide is: Is a probability sample  
21 really needed?

22 And for many people this isn't really an issue.  
23 But a lot of times in observation epidemiology studies  
24 there's other ways to do patient enrollment -- or  
25 participant enrollment. And so it is best to address the

1 issue right up front as to whether or not a  
2 non-probability or convenience sample could be done either  
3 at a statewide or community level. Typically, these types  
4 of studies are easier to conduct, they're cheaper, and  
5 they do have a great amount of internal validity to them.

6           However, the problem is that the results cannot  
7 easily be generalized to a larger population. And there's  
8 a potential bias in selection bias and specific  
9 populations be excluded. And unfortunately in  
10 non-probability samples, you really can't ascertain what  
11 that potential bias is to a great extent.

12                               --o0o--

13           DR. CURTIN: So the next slide says: Well, what  
14 about a probability sample?

15           The interesting thing about probability samples  
16 is they all have some aspects of randomness of selection  
17 to them, which helps you protect against these  
18 uncontrolled sources of variation. But you can also  
19 control other sources of variation in a probability  
20 design. So if you're concerned about a certain  
21 demographic group, you can design the sample to ensure a  
22 certain population size for that demographic group.

23           Typically, from a probability sample, you can  
24 make a valid statistical inference and compare across the  
25 population. You survey the entire population. If there



9 --o0o--

16           You have to determine the population, the type of  
17 survey objectives you have, the mode of data collection,  
18 how you're going to measure these things. So sample  
19 design is just a part of this.

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1 to keep the whole thing within budget.

2 --o0o--

3 DR. CURTIN: So what are the basic steps in  
4 sample design? The next slide you'll see that this is --  
5 basically just about any study design has these types of  
6 basic steps. You start with the study objectives. What  
7 is the content? How are you going to measure these  
8 objectives? What is your target population? Is it the  
9 total population in California? Is it just a county in  
10 California? Is it just a small domain? Is it some sort  
11 of group that crosses like immigrant workers -- immigrant  
12 farm workers? So you define your target population for  
13 the study.

14 Somewhere along the line you make statistical  
15 considerations. What exactly are you going to measure in  
16 terms of a statistic? Are you generating means,  
17 proportions, percentile distributions? And what kind of  
18 precision do you attach to that? What kind of past  
19 statistical power do you want to compare groups?

20 Those types of statistical considerations then  
21 lead to the analytic sample size that you need. So that  
22 gives you the total sample size you need. Then you have  
23 to design a sample to come up with that total sample size.

24 And the sampling statisticians will drive you  
25 crazy coming up with design option after design option

1 after design option. You usually end up with more design  
2 options than you have sample people in your study. But  
3 somewhere along the line you narrow them down and get  
4 focused in on a couple of key issues.

5         For a contaminant biomonitoring type study, one  
6 of the major considerations is the data collection mode.  
7 If you're going to be collecting blood and serum for  
8 people, obviously a mail survey or telephone survey is not  
9 a very feasible mode of data collection. You're going to  
10 have to go out and either go to those people's homes to  
11 collect the information or bring them into some sort of  
12 clinic or examination center to do the blood draws.

13         When you discuss design operations then, you'll  
14 have to keep in count all the costs associated with each  
15 stage of the selection, whether it's fixed costs or  
16 variable costs, and then how that impacts upon the  
17 reliability or the variance at each stage of the  
18 selection.

19         So these things become very complicated. And  
20 even though in classical sample survey textbooks there's  
21 some nice equations, in practice those nice equations  
22 don't hold very well because the cost models or the  
23 variance models aren't as simplistic as they use in the  
24 traditional textbooks.

25         There's always practical and operational issues

1 to deal with. And the biggest thing that you're obviously  
2 dealing with in many of these studies are budget  
3 restrictions. You probably talked about the laboratory  
4 data. Even after you collected the data itself from the  
5 individuals, the processing of the information through the  
6 laboratories to get these measures can be very expensive,  
7 unless they impose a restriction upon the overall study  
8 design.

9 --o0o--

10 DR. CURTIN: So next, what are some of the basic  
11 characteristics of a sample design? Well, what you could  
12 try to do is control the selection for a number of items,  
13 a number of characteristics. You want to be able to get  
14 at whether the population is urban or rural perhaps. You  
15 may want to get at minority populations. You may want to  
16 get at different types of age groups. So, if you do a  
17 simple random sample, those characteristics are coming in  
18 at random and at the level they are in the population.

19 Many times you want to have more -- say, you have  
20 10 percent in an age group. Maybe for the analysis you  
21 need 20 percent in that age group. So you have to have  
22 some mechanism of over-sampling for that age group. And  
23 that's the whole purpose of sample design then, is to take  
24 that total sample size and start breaking up into an  
25 allocation by sample of units and size of units and number

1 of people that you need.

2           Ultimately though when you have these  
3 multiple-stage-selection-type probability designs, the  
4 actual selection itself is at random. And this is what  
5 protects you from an inferential standpoint and this  
6 allows you to make inferences to the general population.

7                               --o0o--

8           DR. CURTIN: So the next slide is this little  
9 diagram. And for your purposes, instead of looking at  
10 this as the United States as stage 1, you should look at  
11 it -- it's about the map of California. The way  
12 multi-stage-area-of-probability designs work is you take  
13 your state or your area and divide it up into smaller  
14 areas typical of primary sampling units. For California  
15 you could have the primary sampling units being the  
16 individual counties in California or they could be census  
17 tracts within the counties. There's a lot more census  
18 tracts than there is counties.

19           But also you then choose a set of those primary  
20 sampling units as your first stage of selection. Then  
21 within that first stage, you get down to lower and lower  
22 levels. You create segments. Maybe segments have a  
23 hundred households in each segment. And maybe you select  
24 20 of those households into your sample. And then out of  
25 each household you select the study participants.

1           And one of the key things that you'll need to  
2 discuss is whether you want to select one person per  
3 household or more than one person per household.

4           But this is a little schematic that shows the  
5 stages of selection that you divide into smaller and  
6 smaller areas, until finally you get down to the  
7 participants. Each stage has a certain probability of  
8 selection attached to it. You can control the selection  
9 so that even though these areas themselves may be  
10 different size, you can control this so that every person  
11 in California has the same probability of being selected  
12 into the sample at least at the start of the study.

13           Onto the next one.

14                           --o0o--

15           DR. CURTIN: The sample design trade-off that  
16 we're most concerned with, that comes up all the time of  
17 course, is cost versus statistical precision. Typically,  
18 to get a decrease in variance or better precision for your  
19 estimates, you're going to have to have a larger sample  
20 size. And so this is kind of the trade-off as you go  
21 through sample design, is trying to make your design more  
22 efficient so that for the same dollars you're getting more  
23 analytic sample size, but at the same time some of the  
24 operational aspects that say you have to cluster the  
25 sample or stratify it in a certain way might be working in

1 the opposite direction. So bottom line is that fixed  
2 budgets tend to fix the sample size that fix the content.

3           So it just gets back to the iterative nature of  
4 sample design. Once you design something, if it's too  
5 expensive, you have to cut it back. And that may be  
6 cutting back on the content because it just may not be  
7 feasible to measure certain items if you don't get  
8 sufficient sample size for your fixed cost.

9                               --o0o--

10           DR. CURTIN: The next slide talks about two terms  
11 of immediate interest. You're probably all familiar, at  
12 least these days, with these voting polls that go out and  
13 they talk about their level of errors, plus or minus 2  
14 percent. Well, that's typically what's called the  
15 standard error. And it gives you confidence intervals  
16 around the estimates, some degree of precision.

17           But in sample design work you're more concerned  
18 with the square of that standard error, or the variance.  
19 So I'll be using terms like "coefficient of variation"  
20 quite a bit, because that's what you're really focusing on  
21 is a variance. And then when you get down to analyzing  
22 it, you need the standard error.

23                               --o0o--

24           DR. CURTIN: So the next slide is the key kind of  
25 concept in sample design. When you do these types of

1 probability designs, you're not getting in the same type  
2 of variance that you would get out of the simple random  
3 sample. There's something called the VIF, the Variance  
4 Inflation Factor or the design effect. And this is  
5 defined as the larger variance you would get under the  
6 complex design divided by the hypothetical variance you  
7 would get as if you could do it as a simple random sample.

8           Now, keep in mind your probability -- that the  
9 probability is that you can't do a simple random sample,  
10 because otherwise you'd have interviewers going all over  
11 the country, it'd be very inefficient, and you'd get so  
12 much smaller sample size for your cost.

13           So the complex design allows you to actually  
14 increase the sample size. But some people mistakenly  
15 interpret this as design inefficiency because the variance  
16 is larger. But when you really consider based upon fixed  
17 costs, it's design efficiency.

18           The impact of weighting and clustering.  
19 Typically, you have to group people into small clusters.  
20 And that has something called the intra-class correlation  
21 coefficient. It means people of similar clusters have  
22 similar measures. And the more they're similar, the  
23 more -- the less sample you get out of a cluster. Now,  
24 this is the same thing you get in multi-stage clinical  
25 trials as well and multi-center clinical trials. All



1 clinical trials are now analyzed as cluster-based  
2 randomization procedures.

3           The effect of differential weighting.  
4 Differential weighting comes in when you try to  
5 over-sample groups. You may sample people at different  
6 rates in order to increase the sample size for specific  
7 domains. Typically, that increases your sampling  
8 variance, you know, somewhere in the order of 6 to 8  
9 percent. So that's not a major factor.

10           The more major factor in increasing the design  
11 effect really is this intra-class correlation coefficient.  
12 So what we do is we look at past studies and use those  
13 past studies to estimate the intra-class correlation  
14 coefficient for an environmental exposure and then apply  
15 it into the sample design work for California to come up  
16 with the overall effective sample size.

17           Now, again, if you're used to doing types of  
18 studies, you know that you come up with a sample size for  
19 your statistical precision as if it was a simple random  
20 sample. But what happens in complex surveys because you  
21 have these Variance Inflation Factors, these design  
22 effects, if you go out and collect 150 people, but the  
23 design effect is 1.5, you really only have the analytic  
24 power of the sample size for 100.

25           And so there's two sample numbers you have to

1 keep track of here. One is the actual number of people  
2 that you're bringing into the sample. And the other is  
3 the actual analytic sample size or effective sample size  
4 that you have to do your analysis.

5 --o0o--

6 DR. CURTIN: Now, the next slide is kind of a  
7 scary slide. This shows the design effects for some of  
8 the laboratory data collected in the NHANES survey. And I  
9 wouldn't be too concerned about this. From an analysis  
10 standpoint, what you're really concerned with is the  
11 relative standard errors associated with these, the  
12 precisions of these estimates.

13 The design effect in this case is actually  
14 somewhat of a misstatement, because that variance for a  
15 simple random sample is hypothetical and there's certain  
16 assumptions that go along with that that are violated in  
17 terms of these actual design effects. What these design  
18 effects are useful is for comparing alternative sample  
19 designs. So if I have three or four different types of  
20 design options, I can get these design effects and even  
21 though they're not appropriate from a simple random  
22 sampling standpoint, they are appropriate for comparing  
23 designs. And I can see if one design, it increases from 9  
24 to 10, or decreases to 8, et cetera.

25 So two things to keep in mind, it's really the

1 relative standard error, that's a precision measurement,  
2 that you're really interested in ultimately from the  
3 sample design standpoint. These design effects are most  
4 useful for comparing relative designs, not so much from  
5 the analysis standpoint.

6 --o0o--

7 DR. CURTIN: And, again -- next slide -- I didn't  
8 put real variables down here because I just wanted to  
9 illustrate a point on design effects by age. What happens  
10 is typically you have various sub-domains. And the design  
11 effect within the sub-domain can be pretty reasonable --  
12 1.2, 1.1, those types of things. But the biometric  
13 measurement may be differing by age, may be increasing  
14 with age or decreasing with age. So when you combine it  
15 in that fashion, you get these design effects that appear  
16 to be much larger. In one case, it's 2.6, another case  
17 it's 9.5. That doesn't really reflect a problem in the  
18 design. That reflects the heterogeneity of the estimate  
19 of the variable you're dealing with by age.

20 So, again, it's of interest from a specific  
21 standpoint in the design of the study; it's not that much  
22 of interest to the total population. That's why you see  
23 these total design effects very large that have to do with  
24 heterogeneity, not design.

25 --o0o--

1 DR. CURTIN: So how do we do sample size?

2 Well, obviously you start with some sort of  
3 statistic, some sort of measured reliability about that  
4 statistic, and convert that into the analytic sample size  
5 you need. You then inflate it by the expected design  
6 effect for your sample design.

7 So if you design -- the analytic sample's 100,  
8 you inflate it by 1.5, it's 150. Well, you know that when  
9 you go out there, not everybody's going to respond to your  
10 study. So you inflate that by the expected response rate  
11 and you come up with a sample size of 200 that you need.

12 Often you'll need several domains. There'll be  
13 males and females, you'll need minority groups. So  
14 there's K domains of interest. So your total sample size  
15 will be that 200 times K. It's a very simplistic way of  
16 doing sample size. In fact, you're a little bit more  
17 complicated. But this gives you the general idea of  
18 having an analytic sample size, you inflate it by the  
19 design effect because of complex design, you inflate it by  
20 your expected response rate, and then you come up with the  
21 total sample size.

22 --o0o--

23 DR. CURTIN: One of the key considerations for a  
24 California study or even a community study is that you're  
25 having these multiple objectives. And one size does not

1 fit all. The design you do for persistent organic  
2 pesticides may not be the best design for flame  
3 retardants. They have different sources of variability  
4 associated with them. They have different intra-class  
5 correlations associated with them. So the sample size is  
6 not the same for every objective.

7           To make the design efficient overall, then you  
8 have to sometimes have a slightly larger sample size for  
9 the multiple objective study than you would have for a  
10 similar single objective study. You would have different  
11 stratification variables for one set of objectives versus  
12 another set of objectives.

13           So when you design these multiple objective  
14 studies, you have to kind of go for the overall  
15 efficiency. And it may not be most efficient for any one  
16 particular variable.

17                               --o0o--

18           DR. CURTIN: The other aspect is that there's a  
19 big difference of whether you're designing a single,  
20 one-time survey versus a continuous survey. When you have  
21 the continuous survey and you know that you can combine  
22 more than one year, then you can get by by having smaller  
23 sample sizes for each year.

24           So a lot of times when people have expensive  
25 studies, they can't get all the budget for one year to do

1 that study in one year, they'll take that study out over  
2 several years, divide the budget over several years and  
3 divide the sample size over several years, and you have to  
4 accumulate sample over time in order to meet all the  
5 analytic objectives.

6 --o0o--

7 DR. CURTIN: So in the next slide, sort of  
8 summarizes the iterative nature of sample design for these  
9 multiple objective studies. You start out by stating all  
10 the objectives, translating statistical measures, coming  
11 up with sample sizes, looking at designs, coming up with a  
12 cost and budget. And then when you're done you have to go  
13 back and either implement the design or start revising  
14 things. Maybe you have to decrease the sample, to  
15 decrease the cost. Maybe you have to change your  
16 statistical requirements on reliability. Maybe you have  
17 to drop components, because it's just not feasible to  
18 measure them. Or maybe you have to change the timeline in  
19 which to get your data. Maybe instead of getting it in  
20 one year, you have to get it in two years.

21 So you go back and forth on the objectives, the  
22 reliability measures, the sample size and the cost until  
23 you've finally come up with something that is in some  
24 sense optimal across all the different objectives in the  
25 study.

1           So that's the basic sample design part of it,  
2 just a very basic sample design.

3           I can take a quick break here for questions or we  
4 can just move onto the statewide survey if you want.

5           MS. HOOVER: Unmute and ask your questions.

6           DR. CURTIN: Okay. Well, hopefully I'm still on  
7 the line.

8           PANEL MEMBER BRADMAN: Gotcha. No, we're just  
9 demuting you.

10          We do have a question.

11          Go ahead.

12          PANEL MEMBER MCKONE: I have a couple of  
13 questions. These are actually not broad, but a little bit  
14 technical.

15          Going back to slide 8. The implication of this  
16 is that area is used. But actually it would seem that  
17 it's some sort of trade-off between capturing the right  
18 population as much as the area. I would guess this is  
19 more focused on populations, that you used geographical  
20 segments really as sort of a tool for finding people, but  
21 ultimately you're driven more by getting the right types  
22 of people, that is, urban or gender or age or something  
23 else as more important, so that the -- the system is  
24 really never designed to get a geographical component. Am  
25 I missing --

1 DR. CURTIN: Well, yes and no. There's  
2 different -- what I didn't go over is there's different  
3 types of what's called sampling frames. You could have a  
4 list of all 36 million people in California and just draw  
5 a sample from the list. In a telephone survey you have a  
6 random-digit-dialing-type frame that pulls people in off  
7 of that. So you can have different ways of coming up with  
8 your sample.

9 What happens in these environmental studies is  
10 typically you have to have a group that's rather  
11 clustered, a group of households all together. And then  
12 you -- so you need an area probability design, so you're  
13 selecting groups of households. And then you backtrack  
14 from that.

15 Now, for the State of California, you can still  
16 ensure geographic representativeness by dividing the  
17 sample of the strata composed of north, middle, south; or  
18 urban, rural; or west coast, east coast of the state. So  
19 you can set in advance the type of stratification variable  
20 that will ensure representation by those characteristics.

21 PANEL MEMBER MCKONE: Okay. We probably could  
22 discuss this more later.

23 The other ones are a little more technical. On  
24 slide 10 and 11, where you're using the coefficient of  
25 variation. I mean the definition on slide 10, isn't that



1 CV squared?

2 DR. CURTIN: Probably.

3 PANEL MEMBER McKONE: Right. CV is the standard  
4 deviation over the mean, whereas the CV squared is  
5 variance. Because the way you're using it in 11, it  
6 almost has to be defined as CV squared on 10.

7 And then this is another question -- probably  
8 interpretation we have to think about, is the Relative  
9 Standard Error as you show it in slide 12, that relates to  
10 the mean. I think we have to be careful that when we're  
11 looking at other percentiles -- and I see this mistake  
12 quite frequently -- is that you can't use the Relative  
13 Standard Error about the mean as a way of expressing  
14 confidence about a high-end exposure, for example, or  
15 high-end individual, because it doesn't play out the same  
16 way if you look at the statistics. So if you wanted to  
17 make it 5th percentile, you'd have to do a different  
18 exercise to get the standard error.

19 DR. CURTIN: Right. Actually, percentile  
20 estimation is pretty complicated. It's not what's called  
21 a linear statistic. It doesn't come out real quickly and  
22 easily from standard software packages.

23 There's something called the Woodruff technique  
24 that was developed. And without getting too complicated,  
25 you have to calculate the empirical distribution function,

1 go back and do the inverse of that to the proportion,  
2 calculate the -- around proportion and do the inverse TDF  
3 and come up with the confidence interval for the  
4 percentile.

5           So, yes, the percentile is not, strictly  
6 speaking, out of this. And if you look at, say, the  
7 environmental report cards that NCEH does, those are not  
8 symmetric confidence intervals that you get about that.  
9 And the definition of standard error is a little bit more  
10 complex for percentile.

11           PANEL MEMBER McKONE: Thank you.

12           CHAIRPERSON MORENO: Other questions?

13           PANEL MEMBER WILSON: Sure.

14           Randy, Mike Wilson. Thank you for your  
15 presentation so far. And two questions.

16           One is, if we know enough in the biomonitoring  
17 arena to understand the differences between inter- and  
18 intra-personal variability in these data, and so in other  
19 words as -- do we know enough if we are tracking a single  
20 individual over time what the variability looks like in  
21 those measurements versus different people at the same  
22 time?

23           DR. CURTIN: Right. The information so far is  
24 rather limited. The NHANES survey is conducted on an  
25 independent sample each year, so you'd have independent

1 people each year. So you don't have the longitudinal  
2 studies on every individual person.

3 Now, there might be some small longitudinal  
4 studies for some specific ones that track the  
5 within-person variation. But that kind of depends upon  
6 the geographic area they're in and their exposures and  
7 what they're dealing with there. So it's not often easy  
8 to extrapolate those to a more statewide population.

9 So you're kind of in an area here where you're a  
10 little bit in the dark. You can get the between-areas and  
11 within-areas, but the within-person is not well known at  
12 this time.

13 PANEL MEMBER WILSON: Okay. And I guess the  
14 second question is about -- you know, that you introduced  
15 at the very beginning, the question of if you follow the  
16 path of a convenience sample, that you then have data that  
17 are not generalizable. And yet on the random samples --  
18 on a random sample design, we end up potentially washing  
19 out or losing the effect of highly exposed subgroups.

20 And I guess this is a -- maybe this is a question  
21 that's better toward the end of the presentation, but I'll  
22 pose it now. And that's just asking you sort of your  
23 judgment on what is appropriate for a State to be  
24 embarking on. If we should be, you know, attempting a  
25 random sample or if we should be really trying, based --

1 you know, looking at the constraints of a State, if we  
2 should really be focused on what we would judge to be  
3 highly exposed subgroups. So you don't need to answer  
4 that I guess now if you don't want to. But I want to pose  
5 that to you as you're proceeding.

6 DR. CURTIN: Well, ultimate I think that's up to  
7 Michael and you guys to kind of determine what the  
8 emphasis should be. Now, in the national study, we're  
9 interested more in sort of the baseline across the United  
10 States and what a reference population might be in an  
11 estimate for the United States, as opposed to an estimate  
12 for an area with a high exposure.

13 This comes up in the Children's Study all the  
14 time, because there we selected the areas at random. But  
15 each site has some impact upon how they're doing their  
16 within-PSU design. And a lot of people, a lot of the  
17 investigators want to select areas that they know have  
18 high exposures. And there's a very valid reason for doing  
19 that obviously. I don't have to go into that. But  
20 there's very valid reasons for doing that. And  
21 convenience samples, if you're looking at something that  
22 is a purely biological model that has no variation by  
23 other factors, then you can get by with doing that.

24 But, again -- this comes up in other countries as  
25 well, whether you have to -- or whether you should be

1 doing it, and especially when you're getting started, and  
2 looking at just high exposure areas and trying to  
3 determine the impacts without those high exposure areas.  
4 You can do it either way. But it's really up to the  
5 people who are responsible for the content of the study to  
6 make that decision.

7 PANEL MEMBER WILSON: Right.

8 Thank you.

9 OEHHA DIRECTOR DENTON: This is Joan. I have a  
10 question.

11 We have built this program on the concept that we  
12 would have 2,000 samples for the statewide survey. So if  
13 you take into account all of those factors that you  
14 whittle down to get, I guess, your effective sample size,  
15 say we just -- I don't know, theoretically we have -- with  
16 2,000 samples we would have an effective sample size of  
17 1,250 or something like that.

18 So looking at a statewide survey with that kind  
19 of effective sample size of 30 million, could you predict  
20 what -- what, will we see a lot of variability in the  
21 samples or -- I mean, what is your judgment as far as that  
22 effective sample size being able to tell us about  
23 statewide biomonitoring concentrations?

24 DR. CURTIN: Keep in mind that for the NHANES,  
25 the national study, we sampled 5,000 people per year and

1 release the data in two-year data cycles, so release it on  
2 10,000 people for a national sample. So 10,000 people are  
3 representing close to 300 million people.

4           However, because these environmental laboratory  
5 measures are so expensive, we limit our age range and take  
6 only about a one-third sub-sample to do the environmental  
7 testing.

8           So our sample size is for the environmentals.  
9 For the national study, as far as raw sample sizes, range  
10 between 1,200 and 2,000 as it is. So if you just make a  
11 very heuristic argument that a sample size of 2,000 has  
12 given you national estimates pretty well, then you can  
13 hopefully think that a sample size of 2,000 is going to do  
14 pretty well at the State level as well.

15           Now, I can get more precise with that and I can  
16 actually, you know, generate estimates with expected  
17 relative standard errors once we get a little bit further  
18 into the sample design.

19           CHAIRPERSON MORENO: All right. Any more  
20 questions from Oakland?

21           OEHHA DIRECTOR DENTON: As you can see, Dr.  
22 Moreno has joined us and has taken over the job as Chair.

23           CHAIRPERSON MORENO: And thank you for chairing  
24 in the interim.

25           PANEL MEMBER BRADMAN: You're welcome.

1 CHAIRPERSON MORENO: Dr. Luderer, are you there?

2 PANEL MEMBER LUDERER: Yes, I am.

3 CHAIRPERSON MORENO: Are there questions from  
4 southern California?

5 PANEL MEMBER LUDERER: I have a question of Dr.  
6 Curtin.

7 My question has to do again with the stage -- you  
8 know, the slide that's dealing with the different stages  
9 of sampling. And so there's this discussion of talking  
10 about, you know, a completely random sample, and the  
11 problems with that being that you might not get enough of  
12 a representation of particular subgroups that you might be  
13 interested in. And so then I just wanted to sort of  
14 clarify this idea of a control selection or the  
15 multi-stage sample design.

16 So when you're going for an example, you have  
17 Stage 1, Stage 2, et cetera. So in my understanding, then  
18 each of these stages the sample size could be either  
19 random or you could have some kind of an over-sampling  
20 within each of those stages as well. If you're, you know,  
21 interested in, per example, if the first stage is  
22 counties, then you could decide that you're going to have  
23 a certain proportion of, you know, urban and rural  
24 counties ahead of time rather than just doing a completely  
25 random sample of all the counties.

1           Am I understanding that correctly?

2           DR. CURTIN: That's correct. And I actually have  
3 some slides -- I have some more on the other stages of  
4 selection and showing how sample size works through there  
5 and how you get to the over-samples. So I should be  
6 answering that question shortly.

7           PANEL MEMBER LUDERER: Okay. Thank you.

8           No more questions on this end.

9           CHAIRPERSON MORENO: Okay. We do have another  
10 question here in Oakland.

11          PANEL MEMBER SOLOMON: Yeah, this is Gina  
12 Solomon. Thanks for the presentation so far.

13          And I got a little stuck on slide 12, which has  
14 the design effects within the NHANES study for '99-2000.

15          DR. CURTIN: Right.

16          PANEL MEMBER SOLOMON: And I guess, you know, the  
17 design effect concept is where I'm not familiar with. But  
18 it did strike me that it seems like the most powerful  
19 design effects are for some of the electrolytes, like  
20 calcium and chloride, that really don't vary a whole lot  
21 across the population.

22          And so how could -- and you pointed out that this  
23 clustering effect that affects -- you know, the people who  
24 are sort of clustered look more similar in terms of their  
25 biomonitoring results. But it wouldn't seem to me like



1 that would explain what's going on here. And so I was  
2 wondering if you could just sort of walk me through the  
3 slide a little bit more so I get the idea.

4 DR. CURTIN: Yeah. And I actually -- at some  
5 point, I hesitated to show that, because I didn't want to  
6 get too hung up on how design effects are calculated.  
7 Because from the standpoint of the sample design itself,  
8 we're more concerned with measures that have design  
9 effects around 2 and 3 as far as design sample. These  
10 measures -- when you see design effects of 34 and 25,  
11 these are somewhat spurious relative to the design. It's  
12 because it's -- even though it's a variance under the  
13 complex design divided by a hypothetical variance under a  
14 simple random sample design, the variance of the simple  
15 random sample is not actually constructed correctly,  
16 because it doesn't really reflect what's going on in the  
17 population.

18 And that's what the hang-up there is. And we  
19 actually, a couple years ago, looked into the components  
20 of that design effect and determined that it really wasn't  
21 designed per se. It was more related to the measurements  
22 themselves and laboratory error, et cetera.

23 PANEL MEMBER SOLOMON: So should we be paying  
24 attention to the design effect number or not?

25 DR. CURTIN: Well, yeah, that's an interesting

1 question. You need to be paying overall questions about  
2 the design effect relative to some of these basic  
3 measures. But some of these laboratory measures, if you  
4 start seeing these very large design effects, you have to  
5 take pause and say, is that something that's really  
6 related to the design or is that really related to just  
7 how they're defined? Okay?

8           And what we do is we sort of break it up into  
9 those variables where we know that it's design specific  
10 versus those where it's definitionally specific, and focus  
11 it on that.

12           So what you have to be concerned with, I believe,  
13 is the overall impact upon clustering to determine whether  
14 you want very small, compact clusters or to spread it out  
15 a little bit more to know whether you want 10 areas within  
16 a county or 20 areas within a county. That's what you're  
17 really looking at. And so you're looking at the key  
18 variables that are affected by that. These things like  
19 calcium and -- no matter what the design, they're still  
20 going to come out that high. They're not just going to  
21 vary that much by the design, because it's something not  
22 related to the design.

23           PANEL MEMBER SOLOMON: Part of what made me  
24 nervous is that right below chloride and calcium are  
25 mercury and lead, which are fairly likely to be part of

1 our biomonitoring study; and, you know, there's an order  
2 of magnitude there. So if we have a sample size of 2,000,  
3 are we really going to gain effectively 200, which is  
4 beginning to seem small, or is that -- you know, can we  
5 perhaps consider those spurious as well?

6 DR. CURTIN: Well, those in particular, lead and  
7 mercury, vary quite a bit by age and sex. And so when  
8 you're doing estimates within age and sex domains, the  
9 design effects for those are actually much smaller. It's  
10 when you combine them for the total population and that  
11 heterogeneity has been taken care of in that definition.

12 So that goes back to the next slide, what I had  
13 by age. That's sort of like the example you see, the  
14 Variable 2 with the overall design -- the total design  
15 affecting 9.5 with the -- specific ones down around 1.5.  
16 That's the situation with lead and mercury.

17 PANEL MEMBER SOLOMON: Got it.

18 Thank you.

19 CHAIRPERSON MORENO: Yes, another question.

20 PANEL MEMBER QUINT: Yes. I have a question.

21 You talked about geographic clustering, you know,  
22 by households. What about the overlay of occupation on  
23 top of that? Suppose, you know, if you sample by counties  
24 and you have certain people living in a certain area but  
25 they have exposures through work that could be quite

1 variable, is there a way to -- how do you account for  
2 that?

3 DR. CURTIN: That's a lot more complicated,  
4 because the occupations are very diverse; unless you have  
5 an occupation like migrant workers that's very -- you  
6 know, kind of defined and geographically defined. If  
7 you're talking about occupational exposures in various  
8 industries, they're somewhat scattered around different  
9 areas.

10 Now, if you could identify strata that's at --  
11 you know, all of these types of segments, all these types  
12 of areas are going to have where all my chemical companies  
13 are. Therefore, chemical workers are there and I can look  
14 at that way. Then you can do it.

15 Otherwise, you have to go with something that's  
16 called a multiple frame study, where you have one frame  
17 which is the area frame and another frame which you would  
18 do from a list of occupations, a list of businesses, and  
19 then you would sample the businesses, and within the  
20 businesses -- you'd sample people within the businesses.

21 PANEL MEMBER QUINT: Thanks.

22 CHAIRPERSON MORENO: Okay. It looks like that's  
23 it for the questions. So shall we continue with the  
24 presentation.

25 --o0o--

1 DR. CURTIN: Yeah. Now, I'm probably -- the next  
2 slide where it says questions is now getting started on  
3 the sample design for CECBP. And, again, I'm probably  
4 going to go into Red Bull overdrive now --

5 (Laughter.)

6 DR. CURTIN: -- and decide to do this rather  
7 quickly, because we've answered some of the questions, but  
8 you're also limited in your time today. And I don't want  
9 to spend too much time on this other than to give you an  
10 opportunity to ask questions on it.

11 So let's go to the start of the design, talking  
12 about characteristics of California, maximum capacity, and  
13 a sample of the sample design.

14 So, first of all, the next slide --

15 --o0o--

16 DR. CURTIN: -- is goals objectives for this  
17 study. The key thing from a sample design standpoint is  
18 that legislation calls for this study, for the California  
19 aspect of it, to be a representative sample with respect  
20 to age, race, ethnicity, and income. So those are types  
21 of things that will have to be controlled for in the  
22 selection to make sure you're adequately represented with  
23 respect to those.

24 And I also note that collection of the  
25 information will involve biological specimens which drives

1 you to one of these area frame cluster designs.

2 --o0o--

3 DR. CURTIN: Under the next slide, the things to  
4 consider -- I've talked about this already -- it's just  
5 related to all these, target populations, precision,  
6 potential stratification variables. Then it goes down to  
7 the level -- the actual State design.

8 --o0o--

9 DR. CURTIN: So the next slide is actually some  
10 information on California. It's the race/ethnic  
11 distribution. And what you would get was an equal  
12 probability sample of 2,000.

13 So in this slide, you see that there's 6.7  
14 percent of the California population -- actually, I forget  
15 what year I used this on. So it may not be 6.7 today.  
16 But whenever I looked at it, it was 6.7 percent. But that  
17 would give you a sample size of 133 out of the sample of  
18 2,000 and is what's called an equal probability design.

19 The Asian population -- and, again, if you're  
20 talking about the Asian population, you may have people  
21 who say, well, that's not one population. It's really  
22 Chinese Americans, Japanese Americans, Korean Americans,  
23 et cetera. But as an entire group, you'd end up with 244  
24 in a sample size of 2,000.

25 Things like Hawaiian and American Indian, with an

1 equal probability sample, you're just not going to get  
2 that many into it and something special would have to be  
3 done.

4 --o0o--

5 DR. CURTIN: In the next slide you see what we do  
6 in the NHANES in terms of all of our stratification and  
7 over-sampling and screening that we do there increases our  
8 sample size from 12 percent Black up to almost 23 percent  
9 in a sample.

10 Mexican Americans, as a whole, across the nation  
11 are much more geographically clustered. You can increase  
12 it by a factor of almost 4 to get that.

13 So this is just an example, given the domain of  
14 interest, how you can actually get more in the sample than  
15 you have in the population. But there's a trade-off, as  
16 you see in the age grouping. If you're going to get more  
17 people less than 20, you're going to get less people age  
18 20 to 39, something along those lines. So whenever you  
19 over-sample one group, you're disproportionately  
20 undersampling another group.

21 --o0o--

22 DR. CURTIN: So the next slide is what are the  
23 pros and cons of over-sampling. Well, unfortunately,  
24 because of the geographic clustering of some of these  
25 characteristics, sometimes in order to over-sample a

1 particular sub-domain, you may be going into highly urban  
2 areas and you lose a lot of the rural sample. Or you may  
3 be going to certain geographic areas in southern  
4 California and you might be losing northern California.

5           So you have to be really concerned on the  
6 trade-off here between the overall geography, other issues  
7 like urban and rural, when you're doing this  
8 over-sampling.

9           And, because you're over-sampling, not all the  
10 controls are for stratification. Typically, you have to  
11 add more households in there than you want and screen  
12 them. And that causes increased costs. In the NHANES  
13 survey, we screen about four households in order to select  
14 one into the family.

15           But you do get better precision for sub-domain,  
16 and you can do statistical testing on disparities in this  
17 way.

18                               --o0o--

19           DR. CURTIN: So the next slide is how a  
20 disproportionate sample might work for California. And  
21 you could actually -- since you have five race/ethnic  
22 groups here, you could put down an unequal probability  
23 sample that's 400 in each group. But it would be very  
24 difficult to do that because of the way the American  
25 Indian population, for example, is clustered in



1 California. So you probably couldn't do that.

2           So this is just an example. Instead of getting  
3 244 Asians, you could, in theory, come up with 400 Asians  
4 in a sample; instead of 133 blacks, you could come up with  
5 400 blacks in a sample.

6           But there's a relative weight. Then each black  
7 person represents 6,000 Californians, each white  
8 non-hispanic person represents 26,000 Californians.  
9 That's not a big issue for some people. But for other  
10 people, they get concerned about it. And it does slightly  
11 increase your overall variance for the total population,  
12 but you're improving the precision for the race/ethnic  
13 sub-domain. So it can be done.

14           Going to the next slide.

15                               --o0o--

16           DR. CURTIN: Again, talking about California, how  
17 would you possibly do 2,000 people in a year? And this is  
18 just a method of operation, a mode of operation. We said,  
19 well, suppose we had 50 weeks per year to move these  
20 people around the country collecting the data -- excuse  
21 me -- moving these people around the state collecting the  
22 data. There's downtime between every community that you  
23 sample where they have to pick up their equipment and  
24 travel. People are limited to five working days per week.  
25 And then the key assumption here is that, given your

1 content, given your questionnaires, given the burden that  
2 you're imposing upon people, you could probably examine 12  
3 persons per day. Given those constraints, you could then  
4 have eight primary sampling units per year, 34 weeks of  
5 data collection, could come up with 2,000 sample persons  
6 per year.

7           So these are the constraints and the operations  
8 that would allow you to come up with 2,000 sample persons  
9 per year and gives you 8 -- if you define counties as  
10 primary sampling units, you could do 8 out of 58 counties  
11 every year in California.

12                               --o0o--

13           DR. CURTIN: The next slide is actually a map of  
14 a selection that I did. And I want to warn you that this  
15 is really not a highly stratified -- I didn't impose all  
16 the control in this. So please you do not ever want to  
17 use this as a sample. I did this when I did the  
18 Children's Study. I designed a sample forum as a sample  
19 and they took it and they ran with it. But this is not  
20 what I would consider a final sample design for  
21 California.

22           It is a sample of a sample. It shows you how the  
23 counties would distribute. And this passes that  
24 statistical criteria called the look test. This looks  
25 like it might be representative of the State of California

1 because it has the nice geographic spread to it.

2 But go to the next slide.

3 --o0o--

4 DR. CURTIN: And this is another realization of  
5 that type of sample design. And now all of the sample  
6 seems to be more or less in the center of the state. And,  
7 you know, you have a large population in Los Angeles,  
8 Orange, and San Diego, and they're not very well  
9 represented in this sample. This is just part of the  
10 vagaries that you get in probability samples. You can get  
11 outlying samples that don't pass the look test.

12 --o0o--

13 DR. CURTIN: The third map, which says the third  
14 two years of the CECBS design, again looks a little bit  
15 better. It still has some geographic variation.

16 Now, what I did for these three maps is I assumed  
17 that there would be a continuous survey over six years.  
18 Obviously, you may not have the budget to do that. But  
19 what I wanted to illustrate was that if you design a  
20 sample this way and you don't get the budget, that first  
21 year or first two years is still a statewide probability  
22 sample. By designing in advance, you have the ability to  
23 roll these samples and combine them.

24 And, in fact, the fourth map --

25 --o0o--

1 DR. CURTIN: -- which is all in red there, if you  
2 combine this as a six-year data set, figuring that you  
3 have -- you're spreading your budget out over six years  
4 and you're collecting this information, you basically  
5 would cover about 85 percent of the population in  
6 California through such a design.

7 Again, this is just a sample of the sample  
8 design. And in working through the cost model and the  
9 budget expectations, maybe California will be able to do  
10 eight areas per year. Maybe they can only do six. And  
11 maybe you won't have six full years of data. But each of  
12 those previous maps is a representative sample of  
13 California. But I did not tightly control the selection.

14 --o0o--

15 DR. CURTIN: Okay. The next slide just talks  
16 about this cumulative sample over time. This is something  
17 that you're going to have to consider in terms of doing  
18 this, whether you want to design a sample for one time  
19 only, and then get budget, design another sample  
20 independently. The problem with that is you might  
21 actually select the same area in two consecutive samples,  
22 which doesn't give you quite as good coverage. The  
23 advantage of selecting a sample over several years is that  
24 you can always cut back and not do the later years of the  
25 study and you still have a representative sample for those

1 that you can afford.

2 And, again, cumulative sample over time, you can  
3 get to more rare events, you can calculate out of  
4 percentiles for some of these estimates that you might not  
5 be able to do in a single year. If the sample sizes are  
6 not large enough for some, maybe combined years gives you  
7 the necessary sample size.

8 And you can also increase the demographic detail  
9 that you're dealing with for smaller and smaller  
10 sub-domains when you combine it over time.

11 --o0o--

12 DR. CURTIN: So that was just a very brief first  
13 stage of how to do a sample design for California.

14 The next group talks about the within-PSU design,  
15 the within-community design, and gets into issues of  
16 segments and households and everything like that. But  
17 I'll take a quick break here to see if there's any  
18 questions on the overall concept of this first stage  
19 design.

20 CHAIRPERSON MORENO: Yes, we have question in  
21 Oakland.

22 PANEL MEMBER McKONE: Tom McKone.

23 It appears that the primary sampling units when  
24 you -- you said that, for example, we have eight that they  
25 were -- that you selected counties randomly until you got

1 a good, as you say, quote, look for the state. Or is  
2 there some other process?

3 DR. CURTIN: Well, again, what I wanted to show  
4 was a map with eight counties on it to show how samples  
5 can look geographically, just to give you an idea of how  
6 they look geographically. If you were actually to do  
7 this, what you would do is you would stratify -- and we've  
8 looked at this. I had other samples, designs done as well  
9 that looked at the 58 counties in California divided into  
10 air basin strata by level of air pollutant. I also looked  
11 at a map of pesticide exposure in California and where the  
12 higher areas of pesticide exposure were, plus the lower  
13 areas of pesticide exposure, that comes off of one of your  
14 websites.

15 In an actual design, those are the types of  
16 pieces of information we use to stratify the sample to  
17 ensure that you're covering those degrees of variability  
18 in your sample design. The only thing I wanted to show  
19 was how they might look on a map.

20 PANEL MEMBER MCKONE: Just kind of thinking out  
21 loud. But as an alternative, couldn't -- I mean the  
22 counties of California are pretty lousy at capturing  
23 anything actually. And as an alternative, couldn't you do  
24 this by census tract, which would then have population  
25 density, so much built into it, and then reorganize it

1 into eight primary sampling units? So in other words, you  
2 would -- instead of starting with counties, you would  
3 start with census tracts, random -- go through some sort  
4 of random selection process, and then see what kind of  
5 coverage you have and then cluster it into -- because they  
6 would -- you know, several of them would be close enough  
7 that they could be lumped together, but you wouldn't  
8 aggregate them. You would just aggregate them in terms of  
9 going out to collect the data. You know, you'd set up  
10 your sampling station in an ideal location for a cluster  
11 of selective census tracts.

12 DR. CURTIN: Right. No decision has been made  
13 yet on how to define what would be primary sampling units.  
14 They could be counties. But as you say, there's certain  
15 issues with counties. The aggregate measures for counties  
16 aren't very good because there's so much variability  
17 within some of the larger counties.

18 You could have census tracts. The way -- for  
19 people not familiar with it, the United States -- every  
20 state is divided into counties, every county is divided  
21 into census tracts, every census tract is divided into a  
22 group of census block groups, and every census block group  
23 is divided up into blocks.

24 So you can build up these geographic units by  
25 looking at census tracts or combinations of block groups

1 or combination of blocks. So you can geographically build  
2 any sort of building block you want that captures the  
3 variation.

4           The amount of information you have is sometimes  
5 questionable, because when people collect data, sometimes  
6 they only collect it at the county level. They might not  
7 have it geo-coded down to the census tract level, so you  
8 may not have some information you need to do the design.  
9 But other -- you know, if you only have county levels for  
10 air pollution data, for example, it's tough to apply that  
11 then back to every census tract within the county.

12           But certainly it is feasible to use smaller units  
13 for primary sampling units as opposed to counties. It's  
14 certainly feasible to do that.

15           OEHHA DIRECTOR DENTON: Randy, I have a quick  
16 question.

17           In one of your earlier slides, did I hear you  
18 correctly? You mentioned that if you over-sample within a  
19 domain, say, the racial domain, that you would make that  
20 up in the age domain? And aren't those separate domains?

21           DR. CURTIN: Well, I had the -- I was using two  
22 different points to illustrate here. You do have to be a  
23 little bit careful, because there is some demographic  
24 difference in age structure between Mexican Americans,  
25 blacks, and whites. Not a lot, but there is some.



1 But the way that particular design was set up,  
2 there's actually 72 sub-domains by age nested within  
3 race/ethnicity. And so that has allowed us to aggregate  
4 the data in that way. Okay?

5 So the actual design was far more detailed than  
6 what I showed there. And the one I showed was only the  
7 margin for age and the margin for ethnicity.

8 So the answer I think is you don't necessarily  
9 impact the age structure by over-sampling for  
10 race/ethnicity. We did it separate -- we did it for both  
11 of them at the same time. And that's why it came out that  
12 way.

13 OEHHA DIRECTOR DENTON: Okay.

14 PANEL MEMBER BRADMAN: I just have a quick  
15 question.

16 Joan, you mentioned -- this is Asa Bradman -- you  
17 mentioned earlier that the program was built around the  
18 idea of 2,000 measurements. And I just want to clarify  
19 the timeframe for that. Measurements per year?

20 OEHHA DIRECTOR DENTON: A person can't hear in  
21 the back.

22 PANEL MEMBER BRADMAN: I'm sorry.

23 I was just asking about the scale of the program.  
24 And Joan had mentioned earlier that it's built around  
25 2,000 -- potentially 2,000 participants. And I wanted to

1 clarify the timeframe for that population. That's 2,000  
2 over two years?

3 OEHHA DIRECTOR DENTON: Yeah, maybe we could  
4 direct that to Michael.

5 Is that every two years, or is that --

6 DR. LIPSETT: Well, we were initially constrained  
7 by the laboratory capabilities where the labs thought that  
8 they couldn't process, especially for the persistent  
9 organic pollutants, more than about a thousand samples a  
10 year. And so we're thinking about two-year cycles with  
11 about 2,000 people.

12 But our thinking about this has evolved somewhat.  
13 So that we might do analyses say at our labs for the  
14 nonpersistents, for example, and the metals, for a larger  
15 sample size. We're thinking now somewhere on the order of  
16 2,000 to 3,000 people per cycle over each two-year period.

17 CHAIRPERSON MORENO: Okay. Other questions?

18 Dr. Luderer, do you have questions down in  
19 southern California?

20 PANEL MEMBER LUDERER: Yes. I have a question  
21 relating to the idea of a cumulative sample over time. So  
22 one of the benefits is that you can get a larger sample  
23 size by doing this cumulating of the sample over time.  
24 But then one thing that seems to me that might be a  
25 possible trade-off was that depending about -- well,

1 depending on the duration of time that you're cumulating  
2 over, couldn't you be getting into issues relating to  
3 population trends -- or I mean trends over time in the  
4 exposure? You know, so the exposure's changing over time,  
5 and then having to deal with that. Or, in addition, also  
6 that your population could be changing over time. So  
7 population movements and, you know, growth or loss of  
8 population in parts of your sampling area.

9 DR. CURTIN: Right. The bigger problem is if  
10 you're dealing with an exposure that's rapidly changing  
11 over time, then you don't particularly want to cumulate  
12 over time. And what you're getting is sort of the average  
13 or the midpoint of that time interval. And if you're  
14 really interested in measuring the trend, then that's not  
15 going to be very well measured when it's changing  
16 over time.

17 So if you've got exposures that are fairly  
18 constant over time, you can accumulate over time. If  
19 you've got something that's changing rapidly, then all's  
20 you're going to get is the midpoint of that, not the  
21 actual trend.

22 PANEL MEMBER LUDERER: Thank you.

23 PANEL MEMBER QUINT: I have a question.

24 So one of the issues also with the cumulating  
25 samples over time is if you publish the data more recently

1 than, you know, the intervals in which you're collecting  
2 samples -- well, I guess I'm confused.

3           When do you actually publish the results of the  
4 sampling data? Because what I'm thinking is that once you  
5 publish the results of the biomonitoring data, there may  
6 be a call for policy change or, you know, intervention in  
7 terms of decreasing the exposures. So it would sort of  
8 affect, you know, the -- you know, some of what you could  
9 say about the kind of cumulative sample, if you understand  
10 what I mean. You know, do you wait until the end to  
11 publish the results or are you publishing the results  
12 every two years, every year, or whatever during that  
13 interval of the cumulative sampling or, you know, storing  
14 of the samples or whatever?

15           DR. CURTIN: Well, that will be up to Michael and  
16 his group to determine the interval for publication. What  
17 it means from a purely statistical standpoint is that  
18 maybe two years of data you could provide estimates for  
19 Mexican Americans in total, but with four years maybe you  
20 can do eight groups within Mexican Americans. So  
21 sometimes it's just a level of demographic detail. More  
22 years, you get better detail.

23           If you've already seen a marked difference in  
24 something, a marked disparity, you bring it and then they  
25 start doing policy and changing exposure levels, the

1 advantage is then that you're in the field over a period  
2 of time and perhaps you can pick that up. This is what  
3 happened when they took the energy crisis several years  
4 ago and gasoline usage went down and we saw a drop in  
5 blood lead levels in the national data, which indicated  
6 that the lead gasoline was an issue. So sometimes being  
7 in the field and monitoring this can actually measure the  
8 impact of the change.

9 CHAIRPERSON MORENO: Any other questions before  
10 we move on?

11 PANEL MEMBER LUDERER: Yes, there's a question  
12 here.

13 PANEL MEMBER CULVER: This is Dwight.

14 If you're doing cumulative studies, can you build  
15 in a nested control for those studies?

16 DR. CURTIN: Okay. I'm not sure I got quite the  
17 question. Could you repeat that?

18 PANEL MEMBER CULVER: Just whether you can build  
19 in a nested control for those cumulative studies?

20 DR. CURTIN: If you have sufficient sample and --  
21 and when you talk about a nested control study, if those  
22 sources of variation in that control study are adequately  
23 measured in the sample itself, you can impose a  
24 quasi-experimental design and get at the information if  
25 the information's there to begin with.

1           So you have to be careful in your questionnaire  
2 development to have all those sources of variation asked  
3 of the participants.

4           PANEL MEMBER CULVER: Thanks.

5           CHAIRPERSON MORENO: Any other questions from  
6 southern California?

7           PANEL MEMBER LUDERER: No more questions.

8           CHAIRPERSON MORENO: Okay. Before we move on  
9 with the remainder of this presentation, I just want to  
10 remind the audience that there will be an opportunity at  
11 the end of this presentation for anyone in the audience or  
12 public to ask questions. If you do, you want to ask some  
13 questions, we have some forms. I think there are blue  
14 cards in the back. And please be sure to fill them out.  
15 And then we'll get to your questions after the completion  
16 of the remainder of the presentation.

17           Okay. Thanks.

18           DR. CURTIN: Okay. I only have, you know, maybe  
19 five or six more slides to just really touch on some of  
20 the issues in a community or within PSU design.

21                               --o0o--

22           DR. CURTIN: So if we go from the slide that says  
23 "Questions" into "Design Issues for Communities".

24           Again, this sort of gets back to the issue of how  
25 you define a primary sampling unit, how do you define a

1 community. You know, is it a contiguous group from a  
2 geographic standpoint? Is it a dynamic group that crosses  
3 the entire state line, but it has some sort of primary  
4 definition to it? And, in particular, once you define  
5 these communities, how are you going to select them? This  
6 hits back to the issue that was raised, well, maybe what  
7 we want to do is select at the start some communities with  
8 very high exposures. And that's fine. You can generalize  
9 that to other areas with similar high exposures, but you  
10 can't generalize it to areas with low exposures. But  
11 that's why that may be what you have to do at the start of  
12 the study.

13           So in any case, in a State design, the  
14 communities are selected at random. Whereas, if you just  
15 get started, you might actually select each community with  
16 more purpose and less at random.

17           Now, once you get to that level, the community  
18 and PSU are sort of the same thing as to how you do the  
19 within-areas design. So for within the design, once you  
20 select an area, whether it's a county or census tract or  
21 whatever, you start defining smaller areas. And you have  
22 to have all these sample size considerations: How many  
23 segments do you have? What are the size of the segments?  
24 How many households do you have per segment? How do  
25 stratify those segments? What's the number that you

1 select? What's the number of households per segment that  
2 you're selecting? And a very key consideration, as I  
3 mentioned, is the number of persons per household.

4 --o0o--

5 DR. CURTIN: For many types of things, two  
6 individuals for the same households are going to have the  
7 same type of exposures. You don't want to do this. For  
8 other reasons, for other exposures, maybe they are highly  
9 different and it actually helps your response rates to  
10 have more than one person per household selected. That's  
11 a sample of design trade-off.

12 As you get into these designs, all of these  
13 sample size numbers have to be figured out how the sample  
14 gets allocated across segments, across households, across  
15 PSUs. Those are all variables in your design that you  
16 have to nail down. And depending upon how you allocate  
17 it, it has different impacts on variance and different  
18 impacts on costs.

19 --o0o--

20 DR. CURTIN: So since I don't have a design in  
21 place for California, the next slide shows how this is  
22 done for NHANES, where we have, in this particular time,  
23 27 areas represented these 3,143 counties in the United  
24 States. We had an average of about 24 or 25 segments per  
25 each of these PSUs for a total of about 700. We screened



1 about 23,000 households for characteristics. So only  
2 about 6,000 of those households are actually entered into  
3 the sample because of their characteristics.

4 We selected on the average of two per household,  
5 so we ended up with 12,000 samples. Out of that, almost  
6 10,000 agreed to be interviewed. And most of the people  
7 that agreed to be interviewed then went on to complete the  
8 MECs -- where overall response rate was 76 percent.

9 So this gives an example then we were screening  
10 households at about a 4-to-1 ratio in order to over-sample  
11 age domain, in order to over-sample race/ethnicity  
12 domains.

13 The next slide.

14 --o0o--

15 DR. CURTIN: Again, segments are typically groups  
16 of census blocks. One household per segment is what we  
17 use at NHANES. The Children's Study actually uses  
18 household size of about 1,200 households per segment, but  
19 that's a very special case. We sampled more households  
20 per segment than we need because we want to -- because of  
21 these environmental exposures, we want a little bit more  
22 spread. Rather than to just have 25 clustered households  
23 all together, we select a hundred and then take a  
24 one-fourth sub-sample. And then that gets -- the set  
25 spreads out the sample a little bit more. So we end up

1 with about 14 people per segment.

2           So even after you do this large study, you're  
3 getting down to these very small areas and only selecting  
4 maybe six households into the sample.

5                               --oOo--

6           DR. CURTIN: So that -- the next slide is impact  
7 of fixed to variable costs. But before I go on to that,  
8 the whole issue then and within community sampling is to  
9 set up smaller and smaller areas, to allocate samples  
10 across those areas, and to do it in such a way that you're  
11 providing coverage for the area at minimum cost, because  
12 that's the key thing in sample design for within PSU  
13 selection or within community selection.

14           Now, there's another slide I put in here, Impact  
15 of Fixed to Variable Costs. This is actually kind of  
16 interesting from a planning standpoint versus a budget cut  
17 standpoint.

18           In doing these types of studies you have a large  
19 fixed cost in order to buy equipment, to gear up to do it.  
20 And then you have the variable cost associated with each  
21 sample person. And this particular example, which is  
22 totally fictitious -- this is not related to any cost  
23 estimates whatsoever for your study, this is just to  
24 illustrate again, -- if you have \$4 million in fixed costs  
25 at \$1,000 per person, then for \$5 million you can do a

1 study of a thousand.

2           You can then argue to your budget people that,  
3 "Gee, for only a \$1 million increase I can collect" -- "I  
4 can increase the sample size from 1,000 to 2,000." And  
5 you might be able to make that case and get the extra  
6 budget you need, because it looks like you're doing so  
7 much better in efficiency to have just a relatively small  
8 increase and double the sample size.

9           Unfortunately, if you design a sample size of  
10 2,000 at \$6 million and then you're told to cut the  
11 budget, you may have to cut the sample by 50 percent in  
12 order to get down to that small budget cut because so much  
13 of the costs are fixed costs.

14           So something to keep in mind when you're planning  
15 to study is that a lot of the costs of doing these things  
16 are in the fixed costs, the infrastructure costs, the  
17 upfront costs. The actual cost of doing the sample is  
18 marginally less than that.

19           And then the cost that I did not put up here,  
20 that Michael mentioned earlier, was the whole processing  
21 costs, the laboratory costs after you collect the data,  
22 how to process it through the labs and come up with a  
23 final data set.

24   --o0o--

25           DR. CURTIN: Finally, ultimately then we come

1 down to the final design parameters that are going to be  
2 required to do any study. And this just circles back to  
3 where we started.

4           You're going to need the content, the types of  
5 statistics you're interested in, the desired level of  
6 statistic reliability of those, and the sub-domains of  
7 interest.

8           There's going to have to be decisions made on  
9 whether you want an equal probability sample with respect  
10 to age, race/ethnicity and sex, or whether you want to  
11 over-sample particular groups.

12           There's going to need to be a decision whether  
13 you want to control the geographic spread of this in urban  
14 and rural or specific counties.

15           And then you're going to have to calculate for  
16 all of the -- and actually then what I do is turn around  
17 and I provide design effects by stage, cost factors by  
18 stage to efficiently design a sample to meet those design  
19 parameters.

20   --o0o--

21           DR. CURTIN: And the final slide is from Dilbert.  
22 And just gives a little indication about the accuracy of  
23 numbers. And you can't read it. It says, "I didn't have  
24 any accurate numbers, so I just made this one up. Studies  
25 have shown that accurate numbers aren't any more useful

1 than the ones you make up." "How many studies showed  
2 that?" "Eighty-seven."

3 (Laughter.)

4 DR. CURTIN: So I'll open up now to any  
5 additional questions.

6 CHAIRPERSON MORENO: All right. Thank you for  
7 the presentation.

8 Questions?

9 Yes, Tom.

10 PANEL MEMBER MCKONE: This is Tom. I hate to  
11 probably be leading off. But this is very interesting,  
12 Randy. I think you've brought up some great points.

13 One of the things that came up, when you were  
14 talking about the segment size and cost and, you know,  
15 translating this to problems we have in California, it  
16 looks like, you know, for California we may not be able to  
17 afford, for example, more than 25 samples within our  
18 households within a segment, or blood samples, say, within  
19 a segment. But actually it doesn't cost that much more to  
20 take 100 blood samples maybe. But it doesn't even double  
21 the cost.

22 Has anyone done a study where you'd do something  
23 like get 100 households or individual blood samples, split  
24 them and then -- for later, but then pool them together?  
25 So you take four and mix them to get, you know, 25

1 samples. Does that cause confusion or does that help out?  
2 Because then you'd have a design where if you're pooling  
3 the blood and you get a really high one, you do have the  
4 option of going in and taking the four that were in that  
5 high pool and looking at them in more detail.

6 DR. CURTIN: Yeah, actually, I just gave a  
7 presentation last Friday to the Joint Canadian, U.S.,  
8 Mexican Group on Human Biomonitoring about the issues of  
9 pooling samples. And there are a lot of statistical  
10 issues involved in what you can estimate once you pool  
11 samples and whether the underlying distribution is normal  
12 or log normals, because you're dealing with geometric  
13 means as opposed to arithmetic means. So there are a lot  
14 of statistical issues in pooling samples. But it's also  
15 driven by not only this kind of concept you had of sample  
16 size, but sometimes you have a limited detection issue.  
17 And for the volume that you've taken, some of the dioxins,  
18 for example, 85 percent are below the limited detection in  
19 the national database. So the concept is to pull the  
20 samples, get additional volume and at least get a measure  
21 for that 85 percent.

22 So I'm trying to jockey it around, because this  
23 is probably a two-hour or a three-hour conversation. And  
24 we're actually scheduled to go down to the Center for  
25 Environmental Health next month to talk to our friends in

1 Atlanta about issues of pooling samples, and we'll bring  
2 that discussion back to Michael at some point.

3 CHAIRPERSON MORENO: Okay. Any more questions?

4 Okay. Dr. Luderer, do have questions in southern  
5 California?

6 PANEL MEMBER LUDERER: No questions here.

7 CHAIRPERSON MORENO: Okay. We're back to this  
8 group.

9 No more questions?

10 If not, I think this is the time to go to the  
11 public, if the public has any questions or comments they'd  
12 like to share.

13 You can come to the mics.

14 DR. ALEXEEFF: The best way to do this -- it's  
15 almost easier sitting down.

16 Hi. This is George Alexeeff from OEHHA. Thank  
17 you very much for the presentation. I have a question,  
18 and I'm trying to formulate it properly in my mind. I  
19 appreciate your example, which you said was fictitious,  
20 where you had a fixed cost and a certain number of  
21 samples. I guess one million for an additional 100  
22 samples or an additional 1,000 samples.

23 But I'm trying to -- I'm wondering if there is a  
24 way of estimating it, what if you had a severe budget cut?

25 So --

1 (Laughter.)

2 DR. ALEXEEFF: -- obviously there's a certain  
3 fixed cost that you have to pay for equipment, you know,  
4 various specific equipment just to measure things. But is  
5 there a way of estimating -- I know that the requirement  
6 is for a representative sample. But if there are  
7 insufficient funds to actually conduct a representative  
8 sample, which we are presuming was 2,000 -- if there was  
9 insufficient funds to do that, is there a point you can  
10 calculate and say, you know, unless we had this amount of  
11 funds we could not do a representative sample? And then  
12 can I ask another question, is a focused sample or a  
13 community-based sample substantially less expensive.

14 I don't know if I've presented it well. I'm just  
15 wondering if that is something that one could calculate or  
16 estimate based just upon funding.

17 DR. CURTIN: Well, we're in the process now --  
18 we, CDC and Michael's group -- of putting together some  
19 very detailed cost models, which look at the different  
20 aspects of the data collection, the different details of  
21 what goes into those cost models. And then these cost  
22 models then form the basis of looking at various design  
23 options. So that type of option could be examined in that  
24 context. Just a -- now, a community study is probably  
25 going to be about the same cost as a PSU in a state study,



1 because you're still doing the same type of things on the  
2 same sort of number of people.

3           But the major difference -- and I'll give you an  
4 example of what's happened in the past at the national  
5 level. Suppose you're rolling along and you collected  
6 half a year of data and then all of a sudden you're told  
7 to stop the data collection. Well, you don't really have  
8 a representative sample, where you needed a full sample to  
9 make a representative. So you have what's left over. And  
10 the question always becomes, "Can I do anything with this?  
11 What sort of analysis can I do with this?" And the answer  
12 is, you can still do something with it; there's still some  
13 types of inference you can make from those partial  
14 samples. There's obviously not as much as you would like  
15 to be able to do, but you don't really lose everything.  
16 You lose a lot, but you don't lose everything.

17           So severe budgets are going to cause severe  
18 problems.

19           But, Mike, I don't know if you want to talk  
20 anything about the cost model itself or just save that for  
21 some other time.

22           DR. LIPSETT: Yeah, I think we'll probably save  
23 that for another time, because we don't have materials to  
24 give the Panel that they can look at.

25           But I think suffice it to say for now, when Randy

1 said it was really detailed, he was not exaggerating.  
2 Yeah, it's a very detailed cost model, including going  
3 down to the costs of disposable supplies and everything,  
4 meaning for sample collection and costs of transporting  
5 the samples. And very, very detailed operational costs.

6 One thing I wanted to mention before the public  
7 comments, I wanted to raise this again --

8 OEHHA DIRECTOR DENTON: You're going to need to  
9 speak up.

10 DR. LIPSETT: Oh, I'm sorry.

11 One thing I wanted to mention again is we would  
12 like to see if there's any interest on the Panel of having  
13 a small subcommittee to meet with our staff on issues  
14 related to study design. And this would include not only  
15 some of the trade-offs that Randy is talking about in  
16 terms of over-sampling and the effective design effect and  
17 analytical sample size, but questionnaire development.  
18 And as you're going to hear later this afternoon, the labs  
19 are in the process of undertaking some pilot studies. So  
20 we want -- we'd like to have a couple, at least two to  
21 three members of the Panel who would be interested in  
22 meeting periodically with us, probably by conference call  
23 or perhaps in person, to discuss some of these issues as  
24 we progress through them.

25 PANEL MEMBER BRADMAN: Michael, are you -- this

1 is Asa Bradman. Are you talking about two or three  
2 different subgroups?

3 DR. LIPSETT: No, one.

4 PANEL MEMBER BRADMAN: Just one. And this one  
5 would focus on questionnaires, laboratory, and design  
6 issues?

7 DR. LIPSETT: Well, mainly design types of  
8 issues. But I'm lumping the questionnaire design as well  
9 within the overall study design issue.

10 And then with respect to the lab pilot studies,  
11 it would be like what kinds of processes the labs would be  
12 needing to pilot test; what are the criteria that we  
13 should apply, for example, with respect to this Request  
14 For Information that's going to be discussed by the labs  
15 later in terms of our analyzing archived samples, because  
16 the laboratories are going to be up and running before the  
17 rest of the sampling design is. So we would have kind of  
18 a broad scope of coverage, this particular -- I mean, we  
19 could have several committees. But that -- I mean,  
20 considering the size of the Guidance Panel, that's really  
21 not going to work.

22 PANEL MEMBER BRADMAN: I'll volunteer.

23 DR. LIPSETT: Thank you.

24 That's one.

25 CHAIRPERSON MORENO: Okay. We have one

1 volunteer. Dr. Bradman.

2 Others interested?

3 PANEL MEMBER KAVANAUGH-LYNCH: (Hand Raised.)

4 CHAIRPERSON MORENO: Two, Marion.

5 CHAIRPERSON MORENO: Others?

6 PANEL MEMBER McKONE: I'm quite interested in the

7 sample -- I mean the statistical design and, you know,

8 what it represents, the population modeling and

9 segmentation.

10 I can't help too much with the questionnaire

11 though.

12 CHAIRPERSON MORENO: Okay. And the staff is

13 recommending four Scientific Guidance --

14 MS. HOOVER: Four total, maximum.

15 CHAIRPERSON MORENO: -- Panel members. We have

16 three volunteers so far.

17 PANEL MEMBER CULVER: This is Dwight Culver. I'm

18 interested in the questionnaire design.

19 DR. LIPSETT: Okay. So we've got four. That's

20 the max that we can have.

21 Okay, great. Thank you.

22 CHAIRPERSON MORENO: Thank you.

23 Thank you, Panel members.

24 Okay. I'm going to ask -- oh, here we go.

25 MS. HOOVER: Any other -- no.

1           PANEL MEMBER MCKONE: Just a comment.

2           You may want to consider splitting it into  
3 questionnaire versus sample design. Aren't they quite  
4 different? In my mind, they are. I mean -- then you'd  
5 have two and two. And, you know, when you're working on  
6 the questionnaire, I don't think I can help much.

7           DR. LIPSETT: Well, I think -- why don't we start  
8 for now with the four, and then we can -- we may want to  
9 split into two smaller subgroups that would be, I'm  
10 assuming, Dr. Kavanaugh-Lynch, Bradman and Culver, and  
11 then the other group would be Dr. McKone.

12           (Laughter.)

13           PANEL MEMBER MCKONE: Less than four.

14           (Laughter.)

15           PANEL MEMBER SOLOMON: If you'd split that way,  
16 then I'd -- you know, I'd be happy -- I'm not fabulous  
17 at study design, but that's the side that I'm more  
18 interested in.

19           PANEL MEMBER KAVANAUGH-LYNCH: And I'm actually  
20 interested in both.

21           DR. LIPSETT: You're interested in both. Okay.

22           PANEL MEMBER MCKONE: Could have it three and  
23 three.

24           PANEL MEMBER SOLOMON: Staff can --

25           PANEL MEMBER MCKONE: We'll go whatever way you

1 think is best.

2 CHAIRPERSON MORENO: Would you prefer to have one  
3 initial meeting and then go from there?

4 DR. LIPSETT: Yes.

5 CHAIRPERSON MORENO: Okay. Of the four?

6 DR. LIPSETT: Yeah. And then we can talk to Dr.  
7 Solomon. After that, if we decide to split it into two  
8 groups, then --

9 PANEL MEMBER SOLOMON: Right. I mean, if you  
10 decide to split into two groups and you're looking for  
11 additional folks for one of the subgroups, consider me,  
12 you know, backup. But if -- I mean, it seems like you've  
13 got a good subgroup now. So if you keep it as one, that's  
14 fine.

15 DR. LIPSETT: Okay. Thank you.

16 CHAIRPERSON MORENO: All right. Then I'm going  
17 to -- I'm going to move forward with questions from the  
18 public. We do have one submitted - Davis Baltz.

19 Welcome back.

20 MR. BALTZ: Thank you.

21 Is this the --

22 CHAIRPERSON MORENO: State your affiliation,  
23 please.

24 MR. BALTZ: Yes. Davis Baltz from Commonweal.

25 Is this also the place to offer a public comment

1 on everything we've heard today or just on the  
2 presentation?

3 CHAIRPERSON MORENO: I think this is a good time  
4 to do it, yeah.

5 MR. BALTZ: Okay. Well, first of all, thank you,  
6 Director Denton and members of the Panel, Dr. Moreno.

7 MS. HOOVER: Speak up a little.

8 MR. BALTZ: Okay. I appreciate the chance to be  
9 with you again.

10 A couple comments on the presentation from Dr.  
11 Curtin. I mean obviously a probability sample would be  
12 preferable so that we have the scientific rigor to back up  
13 policy proposals that might stem from the study. And so  
14 to the extent that those are possible, as a member of the  
15 public who's going to -- has and will track this  
16 carefully, we'd really like to see the results of the  
17 program be statistically strong enough that then proposals  
18 that come forward can have strong backing from across the  
19 spectrum. I think that probably goes without saying.

20 And then a comment that Dr. McKone suggested,  
21 pooling samples to try to save money. Obviously, we'd  
22 need to try to conserve resources. Although, we need to  
23 remember that the statute does provide for individual  
24 study contributors to receive individual results. So if  
25 you pool the samples, you may have to go back and do them

1 again anyway, unless you knew that the people who were  
2 agreeing to have their samples pooled knew they didn't  
3 want their individual results. So, in fact, you would  
4 probably have to do it twice anyway.

5 But all of it comes back to the budget. And Dr.  
6 Lipsett gave the overview slide. I think given the  
7 uncertainty that we have with California's budget  
8 situation -- and I know that the staff of the program have  
9 talked about this -- I think it would be very valuable for  
10 the program to try to generate some data this year that  
11 could be published. And even if it doesn't have the kind  
12 of statistical significance that we would ideally like, it  
13 would really be valuable for the program to publish some  
14 results and -- particularly if it focused on some  
15 communities of concern, so that we could demonstrate to  
16 the Legislature and to the Governor that this program  
17 really is something that the public is interested in. And  
18 that may lead to some opening where additional funding can  
19 be provided so the program cannot only stay at base level  
20 funding, but actually have some increases that will enable  
21 it to get back on its original schedule to publish a  
22 statistically significant study every two years.

23 Right now we're sort of behind schedule, we all  
24 know that, and we all know why. Everyone is willing to be  
25 patient. But with the budget situation as it is, it would



1 just be a shame if the program sort of withered on the  
2 vine because there wasn't sufficient public understanding  
3 of its value.

4           And a final short comment on the budget  
5 situation. The DTSC Toxic Substance Control Account from  
6 which the program is to be funded this year, you know,  
7 maybe that's going to be the better solution over the long  
8 haul than a General Fund line item. We don't know how  
9 this account is going to fare this year and into the  
10 future. So on the surface, the General Fund sounds like a  
11 better bet.

12           But one thing about the DTSC fund is that -- as  
13 we know this program is a collaboration of three different  
14 agencies and offices, two of which are in Cal/EPA and one  
15 of which is Department of Public Health. So I have a lot  
16 of trepidation about the Department of Public Health  
17 having to rely on a Cal/EPA, a DTSC account for its  
18 funding, and is there going to be, you know, the potential  
19 for roadblocks to be put up for the Department of Public  
20 Health to receive the funding that they need to keep the  
21 program on track?

22           So thanks for the chance to comment.

23           CHAIRPERSON MORENO: Do Panel members have any  
24 questions or response to the public comment this morning?

25           Anyone in southern California?

1 PANEL MEMBER LUDERER: No.

2 CHAIRPERSON MORENO: We have one comment here.

3 PANEL MEMBER WILSON: I just have a question now.  
4 Mike Wilson.

5 Davis, your suggestion was to try to generate  
6 initial data, and focusing on, you know, community of  
7 concern of some kind. And I'm wondering if there is -- if  
8 you have suggestions about what that community would look  
9 like. What would be a reasonable focus?

10 DR. LIPSETT: Before Davis responds to this.

11 You are going to hear this afternoon about this  
12 Request For Information that the labs have put out, where  
13 we do want to have the labs analyze some archived samples  
14 from an ongoing epidemiologic study. And that because the  
15 labs are going to have their new equipment installed and  
16 ready to go, hopefully within the next few months, that we  
17 do hope to generate some results within a year after that.  
18 That may not be quick enough for Davis, but -- I don't  
19 know. Davis, do you want to say anything more about it?

20 MR. BALTZ: Yeah. I mean, it's a little bit of a  
21 tricky question, because the program wouldn't want to be  
22 perceived as, you know, cherry-picking a certain community  
23 and prioritizing it over another community that might also  
24 be, you know, very valuable to have a look at.

25 And a small study, we probably wouldn't have

1 statistical significance either.

2 But one idea that I would have would be in the  
3 same way that the program is putting out a request for  
4 collaboration with people who might have samples that  
5 could be biomonitored. The program could potentially put  
6 out a similar sort of, you know, request for interest from  
7 communities who would like to be biomonitored. So I, you  
8 know, would be interested to see some occupational  
9 exposures looked at in more detail for an example. I  
10 think there's a number of Environmental Justice  
11 communities in California who might step forward and have  
12 a geographic focus as a fence-line community, would be  
13 another possibility. Or, you know, certain groups who  
14 have a common disease burden might be another idea.

15 PANEL MEMBER WILSON: Thank you.

16 CHAIRPERSON MORENO: Is that it?

17 OEHHA DIRECTOR DENTON: I think that's it.

18 CHAIRPERSON MORENO: Okay. Well, I'm looking at  
19 the agenda for today. And if there are no more questions  
20 from the public and the Panel on this last presentation,  
21 my recommendation is the Panel could break for lunch.  
22 It's noon now.

23 We have a presentation starting at 1:15?

24 MS. HOOVER: Yeah.

25 CHAIRPERSON MORENO: Is that the time that's

1 recommended that we come back?

2 MS. HOOVER: 1:15.

3 CHAIRPERSON MORENO: 1:15. All right.

4 Any other announcements before we break?

5 No?

6 All right. Thanks.

7 (Thereupon a lunch break was taken.)

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1 AFTERNOON SESSION

2 CHAIRPERSON MORENO: Let's get started,  
3 everybody. Welcome back.

4 Do we have southern California on the line still?

5 Southern California, are you still there?

6 Dr. Luderer?

7 PANEL MEMBER LUDERER: Yes, we're here.

8 CHAIRPERSON MORENO: Great.

9 Okay. We're back at about 1:20. We're going to  
10 get started again.

11 And, at this point, I want to introduce Dr.  
12 Michael Lipsett.

13 Dr. Lipsett.

14 DR. LIPSETT: Okay. Thank you, Dr. Moreno and  
15 Panel members.

16 This morning we heard about a number of the  
17 issues that we've been grappling with with respect to  
18 study design. And this afternoon it's going to be a  
19 briefer, pretty non-didactic session with the two lab  
20 chiefs about where the labs are in this whole process.  
21 They're further along really than the rest of the program.  
22 And they're going to be giving you kind of a progress  
23 report, and then discussing as well this Request For  
24 Information that we have distributed or disseminated to  
25 the research community to try and identify potential

1 university collaborators, so we can analyze some other  
2 types of samples.

3           So making the presentation for Department of  
4 Public Health Laboratory is Dr. Peter Flessel, who's the  
5 Chief of our Environmental Health Laboratory Branch in  
6 Department of Public Health; and Dr. Myrto Petreas, who is  
7 Chief of the -- she's not the chief. That's right,  
8 Bruce -- her supervisor's the Chief of the Environmental  
9 Chemistry Laboratory.

10           DR. FLESSEL: And he's here.

11           DR. LIPSETT: He's here. So --

12           (Laughter.)

13           DR. LIPSETT: Oops.

14           (Laughter.)

15           DR. LIPSETT: Dr. Myrto Petreas will be making a  
16 presentation for DTSC.

17           (Thereupon an overhead presentation was  
18 Presented as follows.)

19           DR. FLESSEL: Thank you, Michael and  
20 distinguished Panel. Thank you for having us back.

21           I have to say, I don't know how you feel about  
22 this, but -- what about this? Does this go in? I hope  
23 so.

24           Every time somebody says the labs are further  
25 along, I kind of have this little chill.

1 (Laughter.)

2 DR. FLESSEL: But we feel like the increments are  
3 important. What we're here to do today is basically  
4 update you on the things that have been happening in the  
5 laboratory. It may not seem all that different than what  
6 you've heard before, but we've been working very hard.  
7 Just the process of getting equipment purchased, huge  
8 effort. So we're eager and we're moving on.

9 --o0o--

10 DR. FLESSEL: Just to remind you, that we are  
11 fortunate to have two labs involved in the program. Our  
12 laboratory in the Department of Public Health will focus  
13 on the nonpersistent organics and the metals. Because  
14 we're looking at nonpersistence, we'll typically be  
15 looking at urine specimens. That's the best way to look  
16 for those kinds of chemicals. And we'll look for metals  
17 best tested in blood.

18 Our lab also has the responsibility for  
19 processing and archiving the samples. So we'll have a  
20 bio-bank eventually within the Department -- within the  
21 program.

22 And then Myrto's lab will focus on persistent  
23 organics, which are best tested in blood and serum because  
24 they are less water soluble, more fat soluble.

25 So we have made progress -- next slide, down

1 south. We're on slide 3 now.

2 --o0o--

3 DR. FLESSEL: We've been able to hire our staff  
4 in both of the departments. There are five in the  
5 Department of Public Health and two in DTSC that are  
6 devoted to this and supported by this program.

7 And we have undergone some remodeling to  
8 accommodate the new lab equipment. And that's almost  
9 done. And here, these slides probably don't impress you  
10 the way they ought to. But right --

11 (Laughter.)

12 DR. FLESSEL: -- right behind Dr. Moreno there is  
13 a space -- a blank space. And if you look very carefully,  
14 you see it's a little different color on the floor. There  
15 used to be a lab bench there, and we got it cut out. And  
16 that was a major step forward. As well as the materials  
17 that you see that are going to be installed, ventilation  
18 material.

19 So it's going -- and, in fact, I should tell you  
20 that one of the -- one small impact -- large for us, but  
21 small for the program -- of the budget impasse was that in  
22 our lab at least the Department of General Services  
23 stopped work without the budget. And they were the  
24 contract that we're bringing to do this.

25 But in a certain way, it helps us, because we had



1 originally thought that we would have the lab completely  
2 renovated and ready to go when the equipment came in, and  
3 then we would just drop it in and go on from there.

4 --o0o--

5 DR. FLESSEL: Actually, it helps that the  
6 equipment is coming in at the same time, because it's  
7 easier to make the renovations when you have the piece of  
8 equipment sitting on the bench. You can know exactly  
9 where it's going to fit. So, in a sense, we lucked out.

10 We have been able to purchase the major pieces of  
11 equipment. They're either arrived -- they've either  
12 gotten here -- here you see some boxes. Proof that at  
13 least one of the instruments has arrived in our warehouse.  
14 This is our new ICPMS. Others will be arriving soon. We  
15 have delivery dates for most of the equipment now.

16 And then we have finished our Memo of  
17 Understanding with the CDC. We signed it just a few weeks  
18 ago. And you have a copy in the -- in your packets, the  
19 Panel does. And I think there are copies on the back  
20 table.

21 --o0o--

22 DR. FLESSEL: The MOU describes the lab support  
23 that CDC will give to the California Environmental  
24 Contaminant Biomonitoring Program in two areas: One, CDC  
25 will provide lab training. They'll also provide analysis

1 of samples for us.

2           The training has to do with learning how to do  
3 their methods at CDC. So we'll be sending staff back to  
4 do that.

5           And, in addition, the process of sample  
6 collection and processing and shipping is complicated.  
7 And having a model to use and getting training from CDC in  
8 those steps is immensely helpful to us, so we don't have  
9 to start from scratch.

10           And then CDC has told us that they will do a  
11 number of kinds of chemical tests for California's  
12 program. First of all, they'll prepare QC samples and  
13 help us with our quality control by providing samples that  
14 have target values, and see how well -- they'll send it to  
15 us blind, and we'll see how we match up with that. That's  
16 very, very valuable.

17           They'll be willing to -- in fact, they have  
18 provided us some expensive standards already for  
19 certain -- from the OP metabolites. We received some  
20 specimens from standards from Dana Barr's lab a couple of  
21 weeks ago.

22           And they'll continue to do that as they're  
23 available, because standards are enormously expensive.  
24 You could spend your whole -- if you wanted to make them  
25 yourself, you could spend your whole life making them. Or

1 if you wanted to buy them, you could spend your whole  
2 budget on that.

3           They have agreed to do a -- support a community  
4 study involving 500 samples for the range of CDC panels.  
5 In other words, CDC's got 10, 15, 20 panels of chemicals.  
6 And as needed, they will do 500 samples. And they'll also  
7 support a one-chemical study that will involve measuring  
8 one specific chemical, PBEs, lead, whatever, in 200  
9 participants. And they'll also do for us something that  
10 they'll -- they've always been willing to do this for  
11 California and anybody else -- any other state -- assist  
12 with exposure incident response. So if we had a major  
13 industrial accident, a rail car derailment, something like  
14 that, where there was major community exposure, California  
15 needed some quick assessment of what might have occurred;  
16 tire fire in Fresno, whatever, they're willing and able to  
17 do that.

18           Now, I should give credit where credit is due.  
19 Behind me sits several people who are much more  
20 responsible for items 2 and 3 under that second bullet.

21           The willingness of CDC to help us with community  
22 studies came out of an initiative that was driven by the  
23 NGOs, which resulted in a letter from Nancy Pelosi to the  
24 Director of CDC, Julia Gerberding. And it was in Dr.  
25 Gerberding's response that she said basically that they

1 would do these things. And so when we sat down to write  
2 the MOU with them, we incorporated those items in. And,  
3 of course, CDC was fully committed to do it.

4 So, again, thank you.

5 --o0o--

6 DR. FLESSEL: Lab challenges remain.

7 You hit me when I'm supposed to pass it over to  
8 you.

9 (Laughter.)

10 DR. FLESSEL: We, in the Department of Public  
11 Health, still do not have operating funds for running the  
12 lab. Chemicals, standards, solvents, glassware, et  
13 cetera, we don't have any in our operating budget.

14 And Myrto's lab has only two staff dedicated --  
15 supported out of the Biomonitoring Program. And this is  
16 well below the critical mass to really drive much  
17 progress.

18 --o0o--

19 DR. FLESSEL: Next steps. I mentioned we're in  
20 the process -- almost in the process of setting up the new  
21 equipment. Followed hard on that will be training of  
22 staff, both with the vendors as well as at CDC. We will  
23 be seeking to develop and validate our methods to meet the  
24 high QA/QC standards that you have to have for this kind  
25 of a program.

1           We'll be sending staff to CDC to get the  
2 training. And we'll be beginning our process to develop a  
3 plan to manage samples and think about how we can increase  
4 throughput.

5                               --o0o--

6           DR. FLESSEL: One small initiative in terms of  
7 actual testing that we've begun to plan for, this is a  
8 collaboration with a health tracking study. Those of you  
9 who have gone back through the story on health tracking --  
10 I know several of you were on the 702 panel -- I emphasize  
11 the need for in the early stages -- health tracking and  
12 biomonitoring should work together. And in the  
13 legislation, in 1379 it says the same thing.

14           So we feel comfortable in responding to an  
15 initiative from the tracking program to assist them with a  
16 pesticide drift study out in Tulare County. This is a  
17 study that has the involvement of local health and  
18 community clinics out there. It's designed to see whether  
19 you can get some information about exposures in these  
20 buffer zones around the fields where there are lots of  
21 people. So the requirement for the study, which came  
22 along before us, was to do very sophisticated GIS mapping  
23 all over California. This is what the tracking program is  
24 so great at. And they were able to indicate where people  
25 are and where pesticides are used.

1           And so, at that point, there was interest in  
2 having the laboratory sit down with them and think about,  
3 "Well, could you do this in so many samples for us," and  
4 so on, as a way of maybe developing better buffer zones  
5 around the fields that are sprayed with pesticides. So  
6 that's where we're trying to plug into that small program.

7           We'll be able to test the collection and  
8 transportation of specimens, in this case urine specimens,  
9 from the field to the Richmond Lab.

10           And then sometime in 2009 -- I can't really tell  
11 you when, but I'm confident we'll get them some results in  
12 the next calendar year -- we will analyze samples from 30  
13 participants that will actually be probably something like  
14 100 specimens all told for the metabolite chlorpyrifos.

15           DR. PETREAS: This morning we heard about the  
16 complexities of choosing the proper sample design and the  
17 resources, and the time it would take to get to the proper  
18 design for a statewide survey as per SB1379.

19           On the other hand, our labs work on a parallel  
20 track trying to build capacity and capability to analyze  
21 the chemical classes that the program would want.

22           And as we get ready and we get our equipment and  
23 we have our methods fully validated, then we would like to  
24 have some real samples so we can produce some real  
25 results. And we have three ways to get -- to work with

1 real samples. And Peter already talked about the health  
2 tracking, one small study that his lab can handle.

3 Last June, we talked to you about obtaining  
4 approval from IRB to conduct a pilot study to test the  
5 laboratory components of the study. And that involves  
6 from selecting the samples, shipping them, labeling them,  
7 making sure the samples arrive to the lab intact. And  
8 then we do our methods and QC and produce valid data.

9 So our project was started with the phlebotomist.  
10 We didn't have any interest in that project on who the  
11 donors are. So, at this point, -- and Michael referred to  
12 that -- we started to develop criteria on selecting  
13 donors, that maybe then the data will make some sense.  
14 And that's where you're invited to help us with this  
15 selection criteria.

16 And we'll talk more about this in December. So  
17 I'm just mentioning this here.

18 Now, a more direct way to get samples directed to  
19 the lab is to go to the freezers. So we want to find  
20 collaborators who already have collected samples and work  
21 with them.

22 So in your packets, you have this copy of the  
23 RFI, the Request For Information, that we sent out. And  
24 in the next slides we'll take you through that.

25 --o0o--

1 DR. PETREAS: So basically the goals that we  
2 described in the RFI is that we want to use the archive  
3 specimens collected in the last few years from California.  
4 We want to use our new equipment and our new validated  
5 methods to produce real data that we can share and see  
6 where we are. An important thing is to see what to expect  
7 when we do the real study, the big study. For the labs,  
8 it's very important to know so we can optimize our  
9 equipment, to make sure we can measure what we need to  
10 measure.

11 So just assessing the ranges of certain chemicals  
12 is very important. And, of course, by doing these  
13 collaborations, we'll be adding value to the ongoing -- or  
14 the original study of the collaborator with whom we're  
15 going to work.

16 Next slide.

17 --o0o--

18 DR. PETREAS: So the RFI describes the  
19 criteria -- objective criteria hopefully to select among  
20 the respondents for one or more collaborators. Basically,  
21 the chemicals that our collaborator would like us to use  
22 to analyze for should be compatible with the ones that the  
23 program wants. And I think it's on page 3 of the RFI  
24 packet we list what we can do now in terms of classes.

25 The samples are very important. What type? We



1 are focusing on urine and blood, because these are the  
2 samples that we'll be using in the program. And from,  
3 again, a lab's perspective, switching matrices and going  
4 to different material is very distracting, and I don't  
5 think it will help us. We really want to stay with blood  
6 and urine.

7           Another important factor is the condition of the  
8 sample, whether it was collected properly for what we want  
9 to use it. There are proper tubes, the proper storage,  
10 handling. So making sure that it was not  
11 cross-contaminated and then the valid samples were  
12 analyzed. That's very important.

13           Of course, population. We assume that the basic  
14 demographic information will be shared with the  
15 collaborators so we can know what to infer. And it's very  
16 important to use a -- or select a population that we can  
17 make some inferences on. So that we want basic criteria  
18 when we judge the proposals.

19           It has to, of course, have sufficient volume to  
20 allow us to do the analysis. But also it has sufficient  
21 sample size -- samples from the sample size to make some  
22 useful, more valuable information.

23           Again, we want to have recent California samples,  
24 taken maybe the last three to five years. And we would  
25 prefer to work with children or pregnant women or other

1 high interest, high-risk groups.

2 Funding, at least partial funding, is one of the  
3 key criteria here. As you heard, we have very limited  
4 resources. So if someone comes with funding, it's a plus.

5 And as with any collaboration, we need to be up  
6 front about data ownership, how we can use the data and  
7 co-authoring papers.

8 --o0o--

9 DR. PETREAS: And, again, the RFI timeline --  
10 next slide. Yes, next slide.

11 This is again from -- this is from the RFI. So  
12 in September we sent out the Request For Information. And  
13 we sent it to everyone we could think of: Academicians,  
14 university researchers, the EPA, the CDC, any contacts we  
15 had, even vendors of equipment and the standards so that  
16 they can spread the word. And, hopefully, we will reach  
17 everyone who may have an interest to respond.

18 So far we haven't had any response yet. But we  
19 still have until November 1st to get the submissions.

20 And then we envision, some time by January, we  
21 should have selected collaborators and start talking with  
22 them. And in February finalize and negotiate and execute  
23 the materials transfer agreements.

24 With a plan that in the spring -- we say March  
25 here -- maybe we'll push that later -- the samples will

1 come to the lab. And the intent is to have approximately  
2 200, 300 samples which we'll analyze. And within a year,  
3 we should have data so we can go back to the Legislature,  
4 as we have to do by 2010 with the first report, and show  
5 something to keep the program alive and keep the interest.  
6 That you heard this morning that we'll have some real  
7 data.

8 Next slide.

9 --o0o--

10 DR. PETREAS: So, in summary, we've heard the  
11 initial hiring has been completed. We're making progress  
12 with renovating the labs, procuring the equipment, setting  
13 them up. We have a plan and so forth.

14 But we still have problems. DPH lab has no  
15 operating money and we have no staff.

16 So with the current resources, we can only do, as  
17 we say, small collaborative studies to test a limited set  
18 of chemicals in small numbers of participants. And  
19 examples we gave is the health tracking, the  
20 collaborations as a response to the RFI, and the pilot  
21 that we can talk about, you know, in December.

22 So in order really to do the statewide or any  
23 large scale study, we need more resources.

24 And that's where we are.

25 CHAIRPERSON MORENO: All right. Well, thank you

1 for the update on the laboratory progress.

2 At this time, any questions from the panel or  
3 speakers?

4 PANEL MEMBER BRADMAN: I have a question. Asa  
5 Bradman.

6 Is part of the criteria for responses to the RFI  
7 be that collaborators can return results to participants  
8 in those freezer-drawn samples?

9 DR. PETREAS: If it's compatible. If the RFI  
10 isn't compatible, you have to talk about that. There are  
11 many things to explore.

12 PANEL MEMBER BRADMAN: But that's not a criteria.

13 DR. PETREAS: We would like to, but it's not an  
14 absolute -- it's not a deal killer.

15 CHAIRPERSON MORENO: We have a few more questions  
16 here.

17 PANEL MEMBER QUINT: Yeah, Julia Quint.

18 I guess I'm a little confused about the budget  
19 situation. This morning it sounded more optimistic, I  
20 guess because I heard what I wanted to hear.

21 (Laughter.)

22 PANEL MEMBER QUINT: But it sounds now that we --  
23 with the presentation by CDC, we don't have the capacity  
24 budget-wise or, you know, resource-wise to do anything  
25 other than this very limited sort of study based on

1 existing samples. Is that not correct?

2 DR. FLESSEL: Certainly, that's correct.

3 PANEL MEMBER QUINT: So -- how do I ask this  
4 question? Because I had the impression with whatever has  
5 happened in terms of releasing -- changing funding sources  
6 or whatever, that there was more optimism about budget  
7 potential or resources. But now I'm hearing that that  
8 isn't true. I'm just a little confused.

9 OEHHA DIRECTOR DENTON: Well, I can just -- maybe  
10 I can just cut to the chase. We are lurching from year to  
11 year on this funding. And right now the baseline, which  
12 includes the resources Michael mentioned, we have to make  
13 sure that we know that baseline is protected. And then  
14 that doesn't include potential growth. We've gone through  
15 all of the internal State procedures one does to increase  
16 the funding and the funding source. But given the state  
17 of the budget, we just -- it's an uncertain time for us, I  
18 guess would be the nicest way to put it.

19 DR. LIPSETT: Julia, can I respond to your  
20 question?

21 PANEL MEMBER QUINT: Yes, please.

22 DR. LIPSETT: One of the things I said this  
23 morning was that there was some good news and that we  
24 were -- our budget was maintained. We were facing a 10  
25 percent cut. In fact, we have had to put in for a 10

1 percent cut as long as we remain part of the General Fund.  
2 But because we did not -- did not stay on the General  
3 Fund, we were not subject to that 10 percent cut.

4 Now, we're looking at a scenario where we -- we  
5 had a new program just getting started and our budget's  
6 hacked by 10 percent if we stayed on the General Fund.  
7 That didn't happen.

8 But the fact remains that the current base budget  
9 does not include operating expenses for the DPH labs. And  
10 the reason for that was that the laboratory people were  
11 trying to be conservative and budget-conscious in their  
12 first budget, because they knew that they would have  
13 equipment that would take awhile to order and be built and  
14 have it be installed, and they were not likely to be  
15 operating the equipment during the first fiscal year. So  
16 they did not include that. They were assuming that they  
17 would get funding for it in the next budget cycle, which  
18 turned out to be an erroneous assumption.

19 So that's why Peter was talking about that really  
20 severe kind of constraint on what they can do at this  
21 point.

22 DR. FLESSEL: I'll give you one other positive  
23 aspect of this funding switch. The Governor when he  
24 signed the budget said, "I'm going to take 400 million out  
25 of general operating in the State." And so that trickles

1 down to various units and divisions and so on.

2           Being over in the DTSC funds this year, we don't  
3 have to deal with those drills, which are coming down all  
4 the time, where they're asking us, well, project what -- I  
5 want another 10 percent, another 15 percent.

6           I had the same reaction that Michael had when we  
7 first heard about this. Oh, my gosh, this is a sort of  
8 replay of something that happened 15 or 20 years ago going  
9 over there. But short-term we feel good.

10           PANEL MEMBER QUINT: Right.

11           DR. FLESSEL: It doesn't build us. But it's  
12 relative, right? It's been down so long, it looks like up  
13 to me.

14           (Laughter.)

15           PANEL MEMBER QUINT: Right. And I haven't been  
16 out long enough to not appreciate what you're talking  
17 about.

18           (Laughter.)

19           PANEL MEMBER QUINT: So the bottom line is we  
20 need to do these short-term pilots to establish and  
21 maintain interest in biomonitoring. So that's imperative,  
22 it sounds to me.

23           DR. PETREAS: To keep the program alive.

24           PANEL MEMBER QUINT: To keep the program alive.

25 It sounds like keep hope alive, but --

1 (Laughter.)

2 DR. LIPSETT: We don't want this to have the same  
3 fate as the hydrogen highway that was so high profile a  
4 couple of years ago.

5 PANEL MEMBER QUINT: Exactly.

6 CHAIRPERSON MORENO: Mike and then Gina next.

7 PANEL MEMBER WILSON: Mike Wilson.

8 Yeah, I just -- first of all, just commend you  
9 for working with what we have rather than sort of saying,  
10 you know, well, the Bill stipulates we have to do a  
11 representative sample; we don't have the funding to do  
12 that, so we're stuck.

13 That leveraging the CDC and leveraging these  
14 other sources and what have you, I think it's just really  
15 commendable and creative.

16 And I guess -- and my question is, if you think  
17 that -- how confident are you that there are samples out  
18 there in the community that we will be able to draw on? I  
19 guess the question is, do you have an indicator that we  
20 have -- that the samples are there?

21 DR. PETREAS: The samples are there. Whether  
22 they're -- we know many resources who have samples there.  
23 Whether they're compatible, whether they want to work with  
24 us, we don't know. Nobody has submitted anything yet.

25 DR. LIPSETT: Although, we've received a number



1 of inquiries from people who are potentially interested,  
2 but we haven't had any formal submissions.

3 DR. FLESSEL: It's a new concept.

4 PANEL MEMBER BRADMAN: You'll get a couple by the  
5 end of the week.

6 (Laughter.)

7 CHAIRPERSON MORENO: All right. Gina.

8 PANEL MEMBER SOLOMON: So I guess I've heard  
9 really four different kinds of study designs that are  
10 really being discussed right now. One is what we heard  
11 about this morning, which is obviously sort of what we're  
12 aiming for in the longer term.

13 And then the others include a CDC community study  
14 of 500 people that they've committed to. And another  
15 being a one-chemical study, which might or might not be  
16 sort of part of the same study that CDC is committed to.  
17 And then the other being these sort of methods development  
18 pilot studies that are the subject of the RFI.

19 And so this morning we created a subgroup of our  
20 Panel to think about that big longer term set of study  
21 design questions. But I guess my question is, since, you  
22 know, we do have these other at least three kinds of  
23 things that are happening and that we -- you know, that  
24 seem more feasible in the near term, should we actually be  
25 throwing some more of our resources as a Panel into trying

1 to really help make those as strong as possible, help, you  
2 know, offer ideas and suggestions for those pieces?

3 DR. LIPSETT: Well, actually, that's what we had  
4 in mind for this Panel, that we would be considering all  
5 these different things and not just the statewide one. We  
6 wanted to surprise you this afternoon.

7 (Laughter.)

8 CHAIRPERSON MORENO: So I have a thought, I  
9 guess. My thought was that the -- this is Ed Moreno --  
10 the big study that the group will be working with staff on  
11 in the design is one thing. But that the subcommittee  
12 would consider the community study, because in some way  
13 they need to be linked. And I think that -- my thoughts  
14 are that the population that defines this community study  
15 and the chemicals that are tested in this community study  
16 would also be the same chemicals that are tested in the  
17 larger Biomonitoring Program so the comparisons can be  
18 made in the future.

19 And then as far as the chemical study, it sounds  
20 like that's a study in response to an exposure event of  
21 some sort?

22 DR. FLESSEL: That's not really a study. That's  
23 an emergency response which CDC would make.

24 CHAIRPERSON MORENO: Okay. And so --

25 DR. FLESSEL: But that's different than the four

1 that we've just described, that Gina just reviewed.

2 CHAIRPERSON MORENO: Then as far as this chemical  
3 study, it's a response --

4 DR. FLESSEL: It's an incident response, not a  
5 study.

6 CHAIRPERSON MORENO: Incident response. Thank  
7 you.

8 But there will be some sampling done? CDC will  
9 come out to provide some sampling among the exposed  
10 population?

11 DR. FLESSEL: No. But we should -- I thought  
12 about not even putting it into my slide. But --

13 CHAIRPERSON MORENO: If there's no sampling, then  
14 okay.

15 DR. FLESSEL: The sampling would be done locally  
16 typically. Somebody -- if it's a train car wreck in your  
17 town, your public health people are probably -- and your  
18 hospital people are probably collecting the samples. And  
19 CDC then takes them home and analyzes the population that  
20 you tell them is probably at greatest risk for exposure.

21 CHAIRPERSON MORENO: Okay. Well, then just --

22 DR. FLESSEL: Different topic completely.

23 CHAIRPERSON MORENO: Okay. Then perhaps the  
24 guidance panels and the programs could maybe keep track of  
25 exposure events as they occur and have an idea of which

1 types of exposure events would trigger a call to CDC,  
2 because the exposure was to chemicals that are also being  
3 tested under the Biomonitoring Program. Then you can  
4 make -- because then you can compare that to the baseline  
5 that's been collected over time.

6 DR. FLESSEL: My response would be that that  
7 activity is completely separate from the biomonitoring  
8 work that we are collaborating on. That is a kind of --  
9 emergency response would occur every once in a while.

10 Dunsmuir: Kid brings a jar of mercury to school,  
11 drops it, and it goes all over the floor. And you've got  
12 a bunch of kids potentially exposed. They want to know  
13 quickly if there was exposure. CDC will help. But that's  
14 not, I think, what we're doing, so it wouldn't matter.

15 CHAIRPERSON MORENO: I know it's not the same.

16 Okay. Those are my thoughts. Thanks.

17 PANEL MEMBER QUINT: This is Julia. I have a  
18 question about the CDC's, you know, commitment to doing a  
19 community study.

20 Does that mean just doing the samples or actually  
21 doing all of the sort of collection of the samples and all  
22 the front part of that part of the study?

23 DR. FLESSEL: We would be involved in the  
24 front-end.

25 PANEL MEMBER QUINT: Right, because that's a big

1 difference. I mean analyzing the samples is a huge  
2 commitment, and that's great. But it sounds like we don't  
3 have money right now to do the front-end of that kind of a  
4 study. Am I not correct?

5 DR. LIPSETT: You are correct.

6 PANEL MEMBER QUINT: Okay.

7 DR. LIPSETT: Yeah. No, the MOU is between our  
8 laboratories and the CDC laboratory. And, you know,  
9 they'll be responsible for the analysis, but not for the  
10 field logistics.

11 PANEL MEMBER QUINT: But we still need the  
12 questionnaires, the door-to-door, whatever else would be  
13 involved in that kind of a study?

14 DR. LIPSETT: Right.

15 CHAIRPERSON MORENO: Okay. Other questions from  
16 the Panel here in Oakland?

17 Yes.

18 We need a microphone next to her.

19 PANEL MEMBER KAVANAUGH-LYNCH: Yes. I'm just  
20 brainstorming here. So you've come up with an RFI to try  
21 to take advantage of researchers' resources and their  
22 access to funding as a way to pilot the screening methods.

23 Could we also possibly take advantage of  
24 community interest and community resources and their  
25 access to funding to start to develop and pilot the

1 recruitment and sample collection and maybe even testing  
2 for community studies? And I'm kind of thinking of the  
3 idea that Davis suggested of some sort of RFP out to  
4 communities to say, gee, are there communities out there  
5 that are interested? And just like you did to  
6 researchers, you said there had to be funding available,  
7 you know. So we -- in RFPs to communities and say if you  
8 can come forward with interest and expertise and funding,  
9 we want to partner with you on -- in doing biomonitoring  
10 in your community.

11 DR. PETREAS: We only focused on the laboratory  
12 here. So the researchers, we have to go to their  
13 freezers -- from their freezers to our freezer. So we  
14 bypassed other equipment and so forth, which takes  
15 resources and --

16 PANEL MEMBER BRADMAN: But in --

17 DR. FLESSEL: And we're so limited. We're just  
18 thinking small. Definitely your idea's a good one.

19 PANEL MEMBER BRADMAN: But in a way, you are  
20 doing that with the chlorpyrifos project in Tulare county.

21 DR. FLESSEL: Well, that's true. But we came in  
22 at the end. We didn't go to them and encourage them.  
23 They came to us and encouraged us.

24 DR. PETREAS: So they were going to do it anyway?

25 DR. FLESSEL: They were going to do it. And they

1 weren't sure how they were going to get the samples  
2 analyzed.

3 DR. LIPSETT: Yeah, I think that's a very  
4 interesting idea. And you're certainly right, that a lot  
5 of NGOs and CBOs could access foundation funding money  
6 that we would not be able to access as State  
7 organizations.

8 So I think this is one -- this is an idea that we  
9 could certainly discuss in the smaller work group too  
10 about how something like that would work, what it would  
11 look like and timeframe and the kinds of objectives. I  
12 think it's a very good idea.

13 CHAIRPERSON MORENO: Julia, did you have any  
14 other questions?

15 PANEL MEMBER QUINT: Well, I wanted to just agree  
16 with that idea, because having talked to a lot of groups,  
17 I think there's wellness and maybe other funding out there  
18 that the State -- we wouldn't be eligible for. But what  
19 would be important is the expertise of, you know, the  
20 researchers and folks here to help -- you know, that would  
21 have to be sort of an in-kind, I would think, in such a  
22 study. I'm not sure how many community groups have, you  
23 know, the kind of expertise that would be needed. But I  
24 may be wrong in that.

25 DR. LIPSETT: Well, another potential hybrid

1 would be to have community groups partnering with the  
2 academicians --

3 PANEL MEMBER QUINT: Right, that's true.

4 DR. LIPSETT: -- to help design that to respond  
5 to such an RFP.

6 PANEL MEMBER QUINT: And we're considering that.  
7 I'm on a work group for the PRHE, the Program on  
8 Reproductive Health and the Environment. And we are  
9 actively looking for those sorts of collaborations right  
10 now. So I think that's an excellent idea.

11 DR. PETREAS: The way we put the RFI was to try  
12 to get samples sooner, because any kind of recruitment  
13 would take funding, would take time. Because we want to  
14 get something within a year.

15 PANEL MEMBER QUINT: Right. I think a parallel  
16 course. Not either/or but parallel.

17 DR. LIPSETT: Yeah, I think that Dr.  
18 Kavanaugh-Lynch was intending for this to be a way that we  
19 could help the program grow, given the constraints that we  
20 have right now fiscally. And it's not something that  
21 would intrude on the RFI at this point.

22 DR. PETREAS: But the bottom line remains, that  
23 the labs can only handle so much. So we can't have both  
24 based and the other and something else.

25 PANEL MEMBER QUINT: No, I understand.



1 CHAIRPERSON MORENO: Okay I'd like to ask Dr.  
2 Luderer if there are any questions from southern  
3 California.

4 PANEL MEMBER LUDERER: We have two questions  
5 here.

6 PANEL MEMBER CULVER: Not so much a question  
7 as -- this is Dwight Culver -- as a comment.

8 I am somewhat familiar with two fairly large  
9 biospecimen banks. And I know that the people that are  
10 responsible for them are very, very stretched for funding.  
11 And to ask them to go into their banks and pull out  
12 specimens -- prepare specimens for shipment, it's going to  
13 cost them money. And they don't have the money to do  
14 that. And so that may be one of the reasons why you're  
15 not getting much of a response with your Request For  
16 Information.

17 CHAIRPERSON MORENO: Any comments?

18 DR. PETREAS: We still have a week.

19 (Laughter.)

20 CHAIRPERSON MORENO: Okay. Other questions?

21 PANEL MEMBER LUDERER: Yeah, I have kind of a  
22 related question, kind of getting back to the RFI and kind  
23 of -- also I think related to Dr. Kavanaugh-Lynch's  
24 suggestion for maybe trying to think of additional  
25 creative ways to partner with researchers and community

1 organizations. And, that is, you know, I understand that  
2 the way -- with the RFI currently, you'd like to have  
3 samples that are already collected, you know, preferably  
4 where there's funding, also currently already available.  
5 But I'm wondering whether it would be possible to, you  
6 know, partner with researchers in terms of maybe  
7 developing proposals, which could then be committed to  
8 actually fund -- you know, to help fund the analyses, and  
9 whether that's something that you might be willing to  
10 consider. Obviously, that's not something that could be  
11 done in a one-year timeframe. But, you know, potentially  
12 in a two-year timeframe something like that might be  
13 possible.

14 DR. FLESSEL: We're definitely interested in  
15 that, sure. The lab certainly is. The program is, right?

16 DR. LIPSETT: Yeah, I -- again, I think this is  
17 something that our new work group would be discussing as  
18 well, because what you're describing would require, you  
19 know, another RF -- either an RFP or an RFI in order to be  
20 able to do something like that.

21 CHAIRPERSON MORENO: Further discussion?

22 PANEL MEMBER WILSON: I want to -- sorry.

23 Thanks, Sara.

24 Mike Wilson. I'm just picking up on Dr. Culver's  
25 point, that I could see how that would be the case in the

1 lab -- in samples that we had worked with in Kathy  
2 Hammond's lab, that, you know, you get your samples and  
3 you catalogue them and store them and it's all laborious.

4           And so extracting those and then releasing them  
5 to an agency would be a large -- it would be a lot of work  
6 and uncertainty, I think, there. So I'm worried that this  
7 idea, which I think is really creative and could be really  
8 helpful, will fail because there won't be a response.

9           And so I guess my question is if it would make  
10 sense, just in thinking about my own experience -- if I  
11 was asked to produce samples, one thing that might be  
12 encouraging for me would be if there was a -- somebody  
13 from the laboratory that would actually come out and help  
14 me do it.

15           (Laughter.)

16           PANEL MEMBER WILSON: And just, you know,  
17 catalogue the samples and ship them. And I guess if  
18 that's within the realm of possibility for the  
19 laboratories, they have to take that on.

20           DR. FLESSEL: Actually, I think an epidemiologist  
21 could do that too.

22           (Laughter.)

23           PANEL MEMBER WILSON: Is there an epidemiologist  
24 in the house?

25           DR. FLESSEL: I think that's -- we'd have to come

1 to some kind of middle ground on that. But, yes. As Gina  
2 said, we can get students to do things like that too.

3 PANEL MEMBER WILSON: Uh-huh.

4 PANEL MEMBER BRADMAN: I related the issue -- and  
5 I think also it might be part of the reason why we haven't  
6 had so many responses, the interest in, you know, having  
7 some financial contribution from other researchers. I  
8 understand the need for that. I know in our situation,  
9 you know, we don't have a line item for that in our  
10 current budgets and we couldn't -- we couldn't do that  
11 without some sort of change with the agency - and, you  
12 know, there's a lot of issues involved, -- or a separate  
13 funding for that.

14 So there is kind of -- there could be some  
15 tension over that if that's a key criteria. And I know,  
16 of course, that everyone is strapped for cash right now.

17 DR. FLESSEL: Well, it is for us because we don't  
18 have an operating budget.

19 DR. PETREAS: Or staff. So we're --

20 PANEL MEMBER CULVER: This is Dwight Culver.

21 CHAIRPERSON MORENO: Yes, go ahead.

22 PANEL MEMBER CULVER: Blood banks sometimes get  
23 rid of out-of-date blood. Can you use any of that for  
24 initial pilot work?

25 DR. PETREAS: How much demographics will there be

1 with a blood bank?

2 PANEL MEMBER WILSON: What is the question?

3 DR. FLESSEL: Why don't we use blood from  
4 outdated blood bank specimens?

5 From a laboratory perspective, we don't know the  
6 difference. Yeah, there may be some program  
7 considerations.

8 CHAIRPERSON MORENO: I think one of the questions  
9 that was brought up was how much demographic information  
10 comes with the sample.

11 DR. PETREAS: From the blood bank.

12 PANEL MEMBER CULVER: Probably not much.

13 DR. LIPSETT: In addition, we would want to make  
14 sure that the samples were collected and stored in a way  
15 that would not promote any contamination with chemicals  
16 that we would be interested in analyzing.

17 PANEL MEMBER McKONE: PVC bags.

18 DR. LIPSETT: Yes, for example, right. There may  
19 be problems with phthalates.

20 CHAIRPERSON MORENO: But thank you, Dwight. Keep  
21 the ideas coming.

22 PANEL MEMBER KAVANAUGH-LYNCH: Well, I think  
23 there'd be serious IRB issues with that. I don't think  
24 you'd -- generally when people are donating blood, they're  
25 not consented for research uses for their blood.

1           PANEL MEMBER BRADMAN:  If it's being thrown away?  
2 Different standards if it's anonymous.

3           CHAIRPERSON MORENO:  I believe Julia has a  
4 question.

5           PANEL MEMBER QUINT:  No, I just wanted to say I  
6 worked for many years in a lipoprotein research, and we  
7 used blood bank blood all the time.  I don't think there  
8 was an IRB issue.  It was -- you know, we isolated  
9 lipoproteins from blood bank blood serum.  So I think  
10 there are researchers -- and I'd be happy to contact the  
11 ones I know who are actually using -- still using blood  
12 bank blood, and they may be able to contribute, you know,  
13 some part of their specimen.  So I could at least look  
14 into that.  I'd be happy to do it.

15           CHAIRPERSON MORENO:  Gina Solomon.

16           PANEL MEMBER SOLOMON:  So to be a little  
17 bit -- yes, Gina Solomon -- to be maybe a little obnoxious  
18 here.  But, you know, like can the DTSC lab lend the DPH  
19 lab, you know, various lab materials that are needed for  
20 doing sample analysis and can the DPH lab lend the DTSC  
21 lab, you know, from time to time a staff person to help  
22 with some analysis?  And are there ways that you guys can  
23 really sort of just throw -- you know, for example, if a  
24 batch comes in that needs to be analyzed, you know, in one  
25 lab or the other, to really sort of pool your resources to

1 get that batch of samples analyzed. And so that's one  
2 question. Because I certainly hope that can happen. That  
3 kind of collaboration should be great.

4           And then the other thing is, should we actually  
5 be talking -- identifying some specific researchers who we  
6 know have really nice, you know, samples in their freezers  
7 and start really bugging them? And is that something that  
8 you're thinking of doing? Should we be doing it as a  
9 panel? I've already, you know, been chatting with some  
10 people. And maybe that's something we should be doing, to  
11 just try to push them to make this a priority. Because I  
12 could see that some researchers may just sort of decide,  
13 well, it's a bit of a pain to do it and there's this whole  
14 form to fill out and it may not meet all of the criteria,  
15 so they just won't get around to it.

16           DR. FLESSEL: Well, I'd respond, first of all --  
17 first question, not obnoxious at all. We've had those  
18 discussions. And, in fact, the first person who brought  
19 it up is Bruce. Where is Bruce La Belle? Bruce said,  
20 "Gee, we should be switching around however we can." Now,  
21 easier said than done. But in principle, we're committed  
22 to that. In practice, we'll see how it works. I mean, we  
23 just want to cross-train in our own lab, and then we'll  
24 think about cross-training in --

25           DR. PETREAS: And we do talk to each other and we

1 do have this --

2 PANEL MEMBER SOLOMON: Yeah, I know.

3 DR. PETREAS: But primarily focusing on certain  
4 instruments and certain matrices, it's more efficient this  
5 way.

6 CHAIRPERSON MORENO: This is Ed Moreno. A  
7 follow-up to that thought.

8 Dr. Denton, there's no reason why Panel members  
9 couldn't personally contact other researchers and make  
10 them aware of the RFI that's out there and the deadline to  
11 submit?

12 OEHHA DIRECTOR DENTON: I think we would  
13 encourage it. Yeah, you bet.

14 CHAIRPERSON MORENO: All right.

15 PANEL MEMBER WILSON: Mike Wilson.

16 And if we were to do that, are you looking for  
17 blood or also for urine samples?

18 DR. FLESSEL: Both.

19 DR. PETREAS: Both.

20 PANEL MEMBER WILSON: Yeah, okay.

21 And then the second is if -- looking at these,  
22 you know, sort of under-resourced entities like  
23 researchers and blood banks and other agencies that would  
24 be out there, have you contacted, you know, for example,  
25 Kaiser or Catholic Healthcare West, these other -- you



1 know, hospitals essentially that would have, you know,  
2 staff and funding to do this? Are they part of the mix?

3 DR. FLESSEL: I don't -- we haven't actively  
4 solicited particular individuals or organizations. But I  
5 did, through a contact with the tracking program, did meet  
6 one of the senior epidemiologists at Kaiser, who said,  
7 "Oh, we have this huge bank and we" -- this bio-bank on  
8 the Hudson somewhere. And I said, "Well, are you going to  
9 submit this?" "You know, I saw their invitation, and I  
10 don't think we'll get around to it." But definitely  
11 they're aware of this interest. It's a question of  
12 getting the right people to sit down with us. So maybe  
13 we'd have to take a more active role in this.

14 MS. LEE: Let me just comment that --

15 CHAIRPERSON MORENO: Identify yourself.

16 MS. LEE: Sorry. This is Diana Lee with EHIB.

17 The RFI went out pretty broadly to maybe roughly  
18 a hundred individuals, organizations, including with a  
19 request also that it be forwarded onto people who may not  
20 know about it directly. So some people may have even  
21 gotten it more than once. And it did go to Kaiser, I  
22 know, for sure. I don't think it went to Catholic  
23 Healthcare West. But if you know of an individual in  
24 particular, we'd be happy to contact that person and send  
25 them something.

1           We did try to send it to heads of researchers or  
2 people who were kind of in that position, who were in a  
3 position to be able to distribute it broadly. But we  
4 certainly -- if you have individuals in particular you  
5 want us to contact directly, please let us know and we'd  
6 be happy to do that.

7           PANEL MEMBER WILSON: Okay.

8           PANEL MEMBER CULVER: This is Dwight Culver  
9 again.

10           How many -- what is the minimum number of samples  
11 that you need for the pilot study?

12           DR. PETREAS: For the frozen archive specimens,  
13 we estimated 200 to 300 individual specimens. And this is  
14 given the resources of the lab.

15           PANEL MEMBER CULVER: Have you thought of going  
16 to clinical laboratories and asking them if you could  
17 piggyback on their activities, getting consent from  
18 patients?

19           DR. PETREAS: One thing we want is to have frozen  
20 samples, not something ongoing. We don't want to rely on  
21 their recruitment process. It will take longer. So  
22 samples which have already been done. It's in the  
23 freezer.

24           PANEL MEMBER LUDERER: This is Ulricke. Just  
25 sort of two questions.

1           One is, are you looking for 200 to 250 specimens  
2 all collected on one study and basically under one  
3 protocol, or that's just the total number of specimens  
4 that you'll be able to analyze and they could be from  
5 multiple studies?

6           And the second question, whether the RFI was sent  
7 to the, you know, contracts and grants offices at all the,  
8 you know, universities in California?

9           CHAIRPERSON MORENO: We'll have an answer for you  
10 in just a minute.

11          MS. LEE: Hi. This is Diana Lee.

12          It went to the Office of the President at UC.  
13 There's a key person there who handles that kind of  
14 distribution of grants information. And the person  
15 escapes my memory -- the name escapes my memory. But my  
16 understanding is that she posted it to a UC researcher  
17 list serve, and it should have been distributed broadly  
18 within the UC system.

19          So I can get you the name of that individual  
20 directly, but I don't have it at hand right now.

21          PANEL MEMBER LUDERER: Yeah, because I don't  
22 recall seeing it. You know, we have a grant newsletter  
23 that -- it's an electronic, and I don't recall seeing  
24 that. And that would be something that would certainly be  
25 worth exploring doing that maybe more directly.

1           MS. LEE: Okay. We can get you the name of that  
2 person and check with her on Monday.

3           DR. LIPSETT: And to respond to your other  
4 question, Dr. Luderer, with respect to whether all the  
5 samples needed to be from the same source. I think the  
6 answer to that is, no, they don't need to be. It would  
7 certainly be more convenient if it were to work out that  
8 way. But we're not -- we don't have a requirement that  
9 they all be from the same group initially.

10          DR. FLESSEL: But, still, I think from a -- this  
11 is Peter Flessel. I guess my thought is that the  
12 laboratory wants to add value to existing epidemiological  
13 studies. So it's not like we're just looking for  
14 specimens to analyze. We want it to add to something  
15 that's going on. And therefore, a study design with some  
16 coherent question with a significant number of samples  
17 would make more sense to us. Although, as far as we're  
18 concerned, one sample looks the same as the next. But we  
19 want it to feed into the larger issue of the program.

20          PANEL MEMBER SOLOMON: This is Gina.

21               My sense is that there's just about half a dozen  
22 researchers in California that have exactly what you want,  
23 you know, one way or another. And so if we just -- you  
24 know, I think this is like six phone calls to get plenty  
25 of samples. And so I'd be happy to help with that and at

1 least give my 2 cents about who those -- you know, who the  
2 people would be.

3 PANEL MEMBER KAVANAUGH-LYNCH: I think the issue  
4 is they want samples and money.

5 PANEL MEMBER SOLOMON: Yeah, but I mean --

6 PANEL MEMBER KAVANAUGH-LYNCH: That's much more  
7 difficult.

8 PANEL MEMBER SOLOMON: Yeah, but I mean I think  
9 very clear that they want -- the lab wants money, but that  
10 it's -- that it is feasible to do this analysis without  
11 getting money from the researchers, as long as the samples  
12 are provided for free. Is that correct?

13 DR. FLESSEL: It's certainly negotiable.

14 PANEL MEMBER SOLOMON: I mean, you'd love to get  
15 money but --

16 (Laughter.)

17 DR. FLESSEL: Yeah, that's correct.

18 DR. PETREAS: But we can't do both the pilot and  
19 the archive and develop methods, and, and, and...

20 PANEL MEMBER SOLOMON: Right. I know.

21 CHAIRPERSON MORENO: Okay. I think the important  
22 thing for the program is to at least get some response.  
23 Because once you get some response, then you have a  
24 process to go through which may involve some negotiation,  
25 if necessary, to come to an agreement so we -- so that we,

1 from the laboratory, can get what it needs. So the  
2 response is the important first step before the deadline.

3 And I also understand though, if necessary, we'd  
4 like to meet the deadline. But deadlines for these can be  
5 extended, right --

6 DR. FLESSEL: Sure.

7 CHAIRPERSON MORENO: -- if necessary?

8 DR. FLESSEL: Yes.

9 MS. LEE: We have sent out a reminder.

10 PANEL MEMBER WILSON: So if we are going to  
11 involve ourselves in this, at this time, who's the  
12 appropriate point person that we would refer to?

13 DR. PETREAS: Marta -- Is it Marta?

14 On the RFI, we have another contact name.

15 PANEL MEMBER WILSON: Oh, it's on the RFI. Okay.

16 DR. LIPSETT: Yeah. In fact, that individual is  
17 here. She's waving her hand in the back. It's Marta  
18 Lutsky --

19 PANEL MEMBER WILSON: Yeah, okay.

20 DR. LIPSETT: -- who's a graduate student in the  
21 School of Public Health, who's working with us on this  
22 program.

23 PANEL MEMBER WILSON: Thank you.

24 CHAIRPERSON MORENO: All right. Any other  
25 comments or questions from southern California?

1 PANEL MEMBER LUDERER: No.

2 CHAIRPERSON MORENO: Julia here has a comment.

3 PANEL MEMBER QUINT: This is Julia Quint.

4 When do you think -- or what is the possibility  
5 of restoring an operating budget for the laboratory?

6 DR. FLESSEL: That will happen when we can  
7 successfully get a Budget Change Proposal through. And  
8 through, in other words in the basic core funding. If we  
9 were able to work with researchers or others to submit  
10 grants, a different story. But we don't have an operating  
11 budget in our current base. That will only happen when  
12 we're successful with a Budget Change Proposal.

13 CHAIRPERSON MORENO: Follow up on --

14 DR. FLESSEL: 2010 is the earliest possible.

15 CHAIRPERSON MORENO: 2010-2011 fiscal year?

16 DR. FLESSEL: Fiscal year '10-'11, right?

17 OEHHA DIRECTOR DENTON: How about nine?

18 DR. FLESSEL: Oh, sorry, nine. I'm living in the  
19 future.

20 DR. LIPSETT: Nine. And we'll have a -- Julia,  
21 as you remember from your years of service in State  
22 government, this is a period of time during which  
23 Department of Finance makes its decisions about various  
24 BCPs. So we should have a sense of that within the next  
25 couple months.

1           PANEL MEMBER QUINT: Right. Yeah, but it just  
2 seems -- I mean, I know for, you know, add-on program sort  
3 of thing. Operating budget for a laboratory sounds so  
4 basic, it just seems to me -- I don't know how you're  
5 operating without a budget to do anything, let alone  
6 biomonitoring. But how can you be a laboratory without an  
7 operating budget?

8           DR. LIPSETT: They do have an operating budget  
9 for other programs, just not for biomonitoring.

10          PANEL MEMBER QUINT: Oh, but not -- now I  
11 understand.

12          All right. It's been too long.

13          (Laughter.)

14          CHAIRPERSON MORENO: All right. Any further  
15 comments from Panel members in Oakland or in southern  
16 California?

17          If not, I'd like to open it up to questions or  
18 comments from the public. I have one blue sheet  
19 requesting public comment.

20          Are there others?

21          Anyone else?

22          By the way, anyone wishing to make public comment  
23 or questions from southern California?

24          PANEL MEMBER LUDERER: No, there isn't.

25          CHAIRPERSON MORENO: Okay. Then I will ask Davis



1 Baltz to come back and provide comment.

2 Thank you for the presentation.

3 MR. BALTZ: Davis Baltz with Commonweal. And  
4 thanks again for a chance to say another comment.

5 It's basically just that, you know, as cosponsors  
6 of this legislation with the Breast Cancer Fund,  
7 Commonweal is committed now and into the future to see  
8 this program not only get off the ground, but build to a  
9 point where it's generating biomonitoring information for  
10 the State on a regular basis in the same way that CDC  
11 does. So if some of these ideas about approaching CBOs  
12 and NGOs and accessing the community resources that we may  
13 be in touch with as well as maybe some funding sources,  
14 we're happy to pursue that conversation.

15 Of course, it's not something that is going to  
16 make this program what it could be over the long term. So  
17 as a stopgap measure, if it's helpful, I hope that we can  
18 continue that conversation.

19 And the only other thing I really want to say is  
20 just express my appreciation to all of the staff from DTSC  
21 and OEHHA and the Department of Public Health, who have  
22 bent over backwards. And I haven't even seen the extent  
23 to which they have done their acrobatics, but I know that  
24 they have really moved heaven and earth to really try to  
25 find solutions, and I just want to express my appreciation

1 to them.

2 And Peter Flessel I know is going to be retiring  
3 soon. And, Peter, maybe you could be called out of  
4 retirement to help catalogue some of those blood bank  
5 samples.

6 (Laughter.)

7 MR. BALTZ: You'll have a lot of time on your  
8 hands, I know.

9 So we look forward to being in touch with all of  
10 you as appropriate in the next meeting in December.

11 So thanks.

12 CHAIRPERSON MORENO: Thank you.

13 Any response from Panel members to public  
14 comment?

15 Okay. Well, I think that's -- oh, sorry, sorry.

16 Gretchen Lee with the Breast Cancer Fund, is that  
17 correct?

18 MS. LEE: Yes. I thank you so much.

19 Well, first I want to really echo my colleague  
20 Davis' appreciation to the staff of the Biomonitoring  
21 Program. You know, I think a lot of the work that they're  
22 doing is probably largely unfunded, and they're giving  
23 really voluntarily to make sure this program gets off the  
24 ground. So I really do want to congratulate them for  
25 their efforts on that.

1           And I really also want to extend my appreciation  
2 to all of you for your continued diligence and your offers  
3 of help today. I think that's fantastic.

4           I'm going to ask for one more -- I'm going to  
5 plea for your help in one other area, if we could. And  
6 the underlying, you know, problem with this program is the  
7 fact that we don't have the funding to get it off the  
8 ground. And we've all been through budget processes and  
9 we all know that they are highly political and contentious  
10 at times. And so I would just encourage the Panel to,  
11 whatever extent it's appropriate and to whatever extent  
12 you feel comfortable, and maybe slightly get out of that  
13 comfort zone, to help the advocates and to help the NGOs  
14 advocate to the Governor, advocate to members of the  
15 Legislature to ensure that this program does get the  
16 funding that it does need.

17           I think, you know, a lot of programs can get the  
18 funding that they do need if just enough people stand up  
19 and speak out for them.

20           It's very easy to rally people around legislation  
21 and to get a program up and running. It is very difficult  
22 to get people together to ensure that that program stays  
23 running.

24           So to whatever extent possible, I would like to  
25 be able to call on you as we go forward in the next few

1 months to ensure the program has the funding that it  
2 needs. And I would just encourage you all to help us in  
3 that regard as well.

4 Thank you.

5 CHAIRPERSON MORENO: Thank you very much.

6 PANEL MEMBER SOLOMON: Actually -- this is Gina.  
7 We had some discussions about this issue at the last  
8 meeting. So I just was a little curious as to where that  
9 stood. I think -- you know, speaking for myself as an  
10 individual, I'm happy to speak out on behalf of the  
11 program. I'm not quite sure where it stood in terms of  
12 our being able to say something as a panel.

13 CHAIRPERSON MORENO: I wouldn't mind -- I don't  
14 mind at all updating the Panel. There was a request --  
15 what I recall, there was a request by the Panel that I and  
16 a group of Panel members -- I think the request was to  
17 approach the Governor or write to the Governor the  
18 importance of the Biomonitoring Program and funding for  
19 the program.

20 And so in reporting back to the Panel, I can tell  
21 you that what we did was we made some phone calls at the  
22 administrative level and some secretary in the  
23 Administration, and determined that I would -- probably  
24 the best, at that time, was to contact the Secretaries of  
25 the Agencies directly and meet with them and also write

1 letters to them and meet directly with the department  
2 heads. And so I did that and provided them in writing and  
3 in person -- or at least by telephone call what the  
4 Biomonitoring Program is, the mandate that exists, what  
5 its mission is, what we hope to obtain, and that we, as  
6 Panel members, would greatly appreciate knowing from  
7 Agency and from the departments what their budget process  
8 is, so that we can, in turn, be more effective at not just  
9 advocating, but intervening at the appropriate time and in  
10 the appropriate manner to try to convince at the Agency  
11 level and at the Department level the need for funding.

12           And so there was effort -- I can tell you there  
13 was a favorable response, an open response by Cal/EPA. I  
14 did try to meet with the Secretary of Health and Human  
15 Services. And, unfortunately, it didn't seem to work out.  
16 I did have a conversation though with Dr. Mark Horton, the  
17 Director of Department of Public Health. And I'm  
18 fortunate enough to meet with him almost monthly. But  
19 this was -- in particular this issue and trying to get to  
20 him while he was still creating his and getting ready for  
21 proposed Budget Change Proposals.

22           But I talked with the Panel members here and in  
23 southern California. Unfortunately I didn't -- I wasn't  
24 as -- I don't think I was as successful with that  
25 department in reaching him before Budget Change Proposals

1 were finalized to submit by that department.

2           So, at this point, I have got to -- what I'm  
3 considering is looking at the next opportunity to raise  
4 awareness and intervene as a panel to the Administration  
5 to try to get funding. And my understanding is the  
6 earliest time -- or next opportunity for us would be after  
7 the January Governor's budget comes out to respond to the  
8 budget and advocate for funding. So that would be as a  
9 panel.

10           Again, now understanding how the Administration's  
11 budget process was moving forward, that would still --  
12 that would provide an opportunity to influence the amount  
13 of funding available for the '09-2010 fiscal year.

14           In terms of 2010-2011, we will need to -- as a  
15 panel, we would need to get back to each of the respective  
16 departments well in advance of, I would say, probably  
17 before August most likely to get Budget Change Proposals,  
18 our recommendations, in for budget for the Department to  
19 consider for the Budget Change Proposal for 2010-2011. I  
20 think we've got that right.

21           So those are the next two opportunities as a  
22 panel as far as I can see.

23           In terms of individual advocacy from Panel  
24 members, any time is a good time for that.

25           (Laughter.)

1 CHAIRPERSON MORENO: So that's my update.

2 OEHHA DIRECTOR DENTON: I think speaking for the  
3 departments, we applaud, we appreciate. It heartens us to  
4 see your support. It's very, very difficult, but, you  
5 know, it's worth fighting for. As we were talking over  
6 lunch, it took us four years to get the program started.  
7 And so, you know, it's something that we're all fighting  
8 for in our different ways.

9 CHAIRPERSON MORENO: Yeah. And I want to thank,  
10 I believe it was, Asa and Julia and Dwight who helped put  
11 that letter together. So I -- where I could, I hand  
12 delivered that letter in the office of the agency heads  
13 myself and sat with them and talked to them about this.

14 PANEL MEMBER SOLOMON: Thank you.

15 CHAIRPERSON MORENO: Um-hmm.

16 All right. I think we're at the point of the  
17 agenda where we've gone over. And we still have -- well,  
18 I was going to introduce, I think, George Alexeeff with  
19 OEHHA.

20 DR. ALEXEEFF: George Alexeeff with OEHHA. So  
21 I'm just providing a short summary of today's meeting.

22 Dr. Lipsett provided an overall update of the  
23 program's activities and budget. And Dr. Randy Curtin of  
24 CDC provided an overview of sample design issues.

25 The Panel formed a subcommittee, which was going

1 to look at the issues of developing a questionnaire and  
2 also study design. And the Panel members were Marion  
3 Kavanaugh-Lynch, Asa Bradman, Tom McKone and Dwight  
4 Culver. And once the subcommittee gets together and  
5 begins to work with staff, there will be some decision  
6 made as to whether this is a two-committee project. And,  
7 at that point, if it does break into two committees, Dr.  
8 Gina Solomon has offered to participate on the Study  
9 Design Subcommittee.

10 We heard an update from Dr. Myrto Petreas and Dr.  
11 Peter Flessel regarding the laboratory activities, the  
12 purchasing of equipment, staff that have been hired, and  
13 their ability to decide what types of analysis they can  
14 perform in each of the laboratories. They've completed an  
15 MOU with the Center for Disease Control regarding lab  
16 support for training and sample analysis. They've  
17 initiated some collaboration with the health tracking  
18 study, looked at a pilot study to test lab components and  
19 to analyze archive samples. And there was a discussion of  
20 a need to do some of these short-term projects to help  
21 develop methods to show incremental progress particularly  
22 with regards to sample analysis. And it was also brought  
23 up that probably study design could also be included in  
24 that.

25 And finally, there was some discussion regarding



1 the value of partnering with academic institutions,  
2 community group, and other organizations.

3 That's it. Thank you.

4 CHAIRPERSON MORENO: All right. Well, thank you.

5 Before we close, one moment.

6 All right, I just want to impose a little bit on  
7 each of the three departments, OEHHA, DPH, and DTS. If  
8 one of the representatives could just go quickly through  
9 the room and identify your staff who've been putting so  
10 much work into this program.

11 Would you like to start.

12 OEHHA DIRECTOR DENTON: Well, let's see. I'm  
13 looking at them right now. George Alexeeff, Lauren Zeise,  
14 Farla Kaufman, Amy Dunn, Gail Krowech, Sara Hoover, who's  
15 the lead under Lauren for this group. And then I think  
16 our newest hire is Rachel Roisman.

17 Do I have anybody else?

18 MS. HOOVER: David Berger in southern California.

19 OEHHA DIRECTOR DENTON: David Berger, of course,  
20 is in Orange County.

21 So that's OEHHA's staff.

22 DR. LIPSETT: Okay. From our department,  
23 actually Peter -- oh, up to the microphone.

24 MS. HOOVER: Got to let everybody hear the whole  
25 meeting.

1 DR. LIPSETT: Okay. Peter Flessel expressed an  
2 interest in identifying the laboratory staff. So I will  
3 just identify non-laboratory staff who are from --

4 (Laughter.)

5 DR. LIPSETT: Not very good with these logistics.

6 So from our department, people in the  
7 Environmental Health Investigations Branch who were funded  
8 solely with biomonitoring money are Diana Lee and Robbie  
9 Welling. You want to -- just a second. I want you to  
10 raise your hands. And Philip Gonzaga at the back. And  
11 then others who are, I guess, contributing time include  
12 myself, Sharon Lee, Lori Copan, Sandy McNeel, and Marta  
13 Lutsky.

14 DR. FLESSEL: So we have three of the four --

15 CHAIRPERSON MORENO: It works.

16 DR. FLESSEL: Three of the four laboratory staff  
17 supported by the program are here. Jianwen She, right  
18 there. Next to him, Paramjit Behniwal. And right behind  
19 Paramjit is Bob Ramage. Frank Barley is in Portland,  
20 Oregon. But he's here in spirit. And then the one member  
21 of the staff who supports us is a staff services analyst  
22 by the name of Meralda Rafol. She's not here.

23 DR. PETREAS: From DTSC, the two funded staff,  
24 Miaomiao Wang and Yunzhu Wang, are in the lab working.

25 (Laughter.)

1 DR. PETREAS: And not in the laboratory, Dr.

2 Bruce La Belle and I, who contribute our time here.

3 CHAIRPERSON MORENO: All right. Well, thank you  
4 very much for that. And I appreciate all the work that  
5 goes into these meetings. And I'm sure the Guidance Panel  
6 greatly appreciates the opportunity to come in and get  
7 down to business as a panel to work with you.

8 At this point, I was asked to remind the Panel  
9 program and the public that we have a meeting in December.  
10 And I believe it's been decided that it will be a half day  
11 meeting December 4th, which --

12 MS. HOOVER: Yes, December 4th.

13 CHAIRPERSON MORENO: And then followed by a  
14 full-day meeting December 5th, on a Friday. And that the  
15 Panel members should have received an Email to make -- or  
16 a suggestion of where to make hotel reservations.

17 And that the focus of the meetings will -- I  
18 believe the December 5th focus will be on chemical  
19 selection. But there's going to be continued discussion  
20 on the day -- prior day, December 4th, some follow-up on  
21 today's activity and hopefully some -- maybe some reports  
22 back on the committees that have been formed and the  
23 activities of the committees.

24 DR. ZEISE: And it'll start around 2 on the 4th.

25 CHAIRPERSON MORENO: Okay. So December 4th

1 meeting starts at 2.

2 DR. ZEISE: In Sacramento.

3 CHAIRPERSON MORENO: In Sacramento. I'll be  
4 there.

5 (Laughter.)

6 CHAIRPERSON MORENO: And I think that's it.

7 So if there are no -- are there any other  
8 comments by Panel members, program staff?

9 If not, I believe that that's it for the meeting  
10 for today.

11 Thank you, everyone.

12 (Thereupon the California Environmental  
13 Contamination Biomonitoring Program  
14 Scientific Guidance Panel meeting  
15 adjourned at 2:37 p.m.)

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